HEMPSONS

DATED **12th March 2021**

LANCASHIRE & SOUTH CUMBRIA NHS FOUNDATION TRUST

and

XXXXXX (pharmacy details to be added)

SUB-CONTRACTING AGREEMENT

FOR

Smoking Cessation Services

CONTENTS

CLAUSE

SCHEDULE

THIS AGREEMENT is dated 1st April 2021

PARTIES

(1) **LANCASHIRE & SOUTH CUMBRIA NHS FOUNDATION TRUST** of Sceptre Point, Sceptre Way, Walton Summit, Preston, PR5 6AW (**Main Contractor**).

(2) XXXXXXX Pharmacy details and address o be added here

BACKGROUND

(A) The Main Contractor has entered into an agreement (the Main Contract, as defined in clause 1.1) under which the Main Contractor agrees to provide Smoking Cessation Services on behalf of Lancashire County Council (**The Authority**).

(B) The Main Contractor may only sub-contract on terms approved by the Authority. This Agreement has been approved by the Authority.

AGREED TERMS

1. INTERPRETATION

The following definitions and rules of interpretation apply in this agreement.

1.1 Definitions:

control: shall be as defined in section 1124 of the Corporation Tax Act 2010, and the expression **change of control** shall be construed accordingly.

day: a period of 24 consecutive hours ending at 12.00 midnight.

Main Contract: the agreement attached as Schedule 1.

Scope of Work: the specification set out in Schedule 2.

1.2 Clause, Schedule and paragraph headings shall not affect the interpretation of this agreement.

1.3 Except as provided expressly in this clause 1 of this agreement, terms as defined in the Main Contract shall have the same meaning when used in this agreement.

1.4 Except as provided expressly in this agreement, the rules of interpretation in the Main Contract shall apply to this agreement.

1.5 For the purposes of this agreement, and unless the context otherwise requires, references in the Main Contract to "this agreement" shall be to the Main Contract as incorporated into this agreement, with the alterations made for the purposes of this agreement.

1.6 In this agreement:

(a) any reference to a "clause" or "Schedule" is, unless the context otherwise requires, a reference to a clause or Schedule in this agreement, excluding a clause or schedule in the Main Contract; and

(b) any reference to a "Main Contract clause" or "Main Contract Schedule" is, unless the context otherwise requires, a reference to a clause or schedule in the Main Contract.

1.7 A **person** includes a natural person, corporate or unincorporated body (whether or not having separate legal personality) and that person's personal representatives, successors and permitted assigns.

1.8 The Schedules form part of this agreement and shall have effect as if set out in full in the body of this agreement. Any reference to this agreement includes the Schedules.

1.9 A reference to a **company** shall include any company, corporation or other body corporate, wherever and however incorporated or established.

1.10 Unless the context otherwise requires, words in the singular shall include the plural and in the plural shall include the singular.

1.11 Unless the context otherwise requires, a reference to one gender shall include a reference to the other genders.

1.12 A reference to any party shall include that party's personal representatives, successors and permitted assigns.

1.13 A reference to a statute or statutory provision is a reference to it as amended, extended or re-enacted from time to time.

1.14 A reference to a statute or statutory provision shall include all subordinate legislation made from time to time under that statute or statutory provision.

1.15 A reference to **writing** or **written** includes fax and email.

1.16 Any obligation on a party not to do something includes an obligation not to allow that thing to be done.

1.17 A reference to **this agreement** or to any other agreement or document referred to in this agreement is a reference to this agreement or such other agreement or document as varied or novated (in each case, other than in breach of the provisions of this agreement) from time to time.

1.18 Any words following the terms **including**, **include**, **in particular**, **for example** or any similar expression shall be construed as illustrative and shall not limit

the sense of the words, description, definition, phrase or term preceding those terms.

2. EFFECTIVE DATE

2.1 This agreement shall have legal effect from 1st April 2021

3. COMMENCEMENT AND DURATION

This agreement shall be effective from the Effective Date and shall continue in force until the parties have discharged all their obligations under it unless:

(a) the Main Contract is terminated for any reason, in which case this agreement shall terminate immediately and automatically, without further action being necessary by the parties, and subject to all the rights of the parties accrued up to the date of termination; or

(b) this agreement is terminated by one of the parties under clause 9.1.

4. SUB-CONTRACTING AGREEMENT

4.1 As soon as this clause becomes effective under clause 2 above, the Subcontractor shall discharge in full the duties imposed upon the Main Contractor in the Main Contract in respect of the Scope of Work set out in Schedule 2 of this agreement. Except as provided in this agreement, the Main Contract shall be used to determine the respective rights and duties of the Main Contractor and the Subcontractor under this agreement except that:

(a) wherever in the Main Contract there is a reference to the Authority or a term referring to the Authority, for the purposes of this agreement a reference to the Main Contractor or a term referring to the Main Contractor shall be substituted;

(b) wherever in the Main Contract there is a reference to the Main Contractor or a term referring to the Main Contractor, for the purposes of this agreement a reference to the Subcontractor or a term referring to the Subcontractor shall be substituted; and

(c) the Main Contract shall be interpreted subject to the further provisions of this agreement and as set out in Schedule 2 and Schedule 3.

5. INDEMNITY FROM SUBCONTRACTOR AND DISPUTES

5.1 The Subcontractor shall indemnify the Main Contractor against all losses, claims, demands, costs and expenses incurred or suffered by the Main Contractor including all claims for liquidated damages by the Authority against the Main Contractor arising out of the Scope of Work.

5.2 The Main Contractor shall give to the Subcontractor notice in writing as soon as possible after it becomes aware of any dispute between the Main Contractor and the Authority arising out of the Scope of Work.

5.3 At the written request of the Main Contractor, the Subcontractor shall deal with any disputes that arise between the Main Contractor and the Authority arising out of the Scope of Work and shall control and pay in full for any litigation, arbitration, mediation, adjudication, expert determination or other dispute settlement procedure in which the Main Contractor might be involved as a result of entering into this agreement and the Main Contract. Following such request, and until further notice from the Main Contractor, the Subcontractor shall be deemed to have sole authority to manage and settle such dispute. The Main Contractor may withdraw such authority on reasonable written notice.

5.4 The Subcontractor shall:

(a) pay to the Main Contractor the amount of all costs and expenses (including legal, and out-of-pocket expenses) reasonably incurred by the Main Contractor in connection with the negotiation, preparation, execution and perfection of this agreement and any other document referred to in it; and

(b) on demand, pay to the Main Contractor the amount of all costs and expenses (including legal, and out-of-pocket expenses) incurred by the Main Contractor in connection with enforcing or preserving any rights under, or monitoring the provisions of this agreement, and any other document referred to in it.

5.5 The Subcontractor shall pay the Main Contractor any amounts due to the Main Contractor within 30 days of date of invoice, unless otherwise stated in this agreement.

6. FEES, CHARGES AND EXPENSES

6.1 The Main Contractor shall pay to the Subcontractor as full consideration for the performance by the Subcontractor of its duties under this agreement the amounts set out in **Error! Reference source not found.** At the times specified in Schedule 6

6.2 The Main Contractor may at any time and at its option, without notice to the Subcontractor, set off any liability of the Subcontractor to the Main Contractor (including any amounts due under clause 5 above) against any liability of the Main Contractor to the Subcontractor, whether either liability is present or future, liquidated or unliquidated, and whether or not either liability arises under this agreement. Any exercise by the Main Contractor of its rights under this clause shall not limit or affect any other rights or remedies available to it under this agreement or otherwise.

7. COMPLIANCE WITH LAWS AND POLICIES

7.1 Each party shall at its own expense comply with all laws and regulations relating to its activities under this agreement, as they may change from time to time, and with any conditions binding on it in any applicable licences, registrations, permits and approvals.

7.2 The Subcontractor shall comply with any polices as the Main Contractor may reasonably notify to them from time to time;

7.3 The receipt, storage and sharing of patient identifiable data shall be undertaken as set out in schedule 5

7.4 The agreed process may be altered by the prime provider subject to alternative information sharing processes being developed

7.5 The subcontractor is expected to achieve compliance with the Information Governance Toolkit Standard as soon as possible during year 1

7.6 The subcontractor is expected to establish and maintain a dedicated NHSMail inbox for the secure sending and receiving of referral information

8. LIMITATION OF LIABILITY

8.1 Nothing in this agreement shall limit or exclude the liability of either party for:

(a) death or personal injury caused by its negligence, or the negligence of its employees, agents or subcontractors (as applicable);

(b) fraud or fraudulent misrepresentation or wilful default; and

(c) any matter for which it would be unlawful to exclude or restrict liability.

8.2 Subject to clause 8.1:

(a) Neither party shall under any circumstances whatever be liable to the other, whether in contract, tort (including negligence), equity (including restitution), breach of statutory duty, or otherwise, for:

(i) any loss of profit, loss of revenue, loss of use, loss of goodwill, loss of data, loss due to interruption of business, or loss of anticipated savings, whether direct or indirect, and even if the party has been advised of the possibility of such losses or damages;

(ii) any loss that is an indirect consequence of any act or omission of the other party; or

(iii) any *ex gratia* payment or sum paid in settlement of a claim paid by one party without the prior written approval of the other.

8.3 The Main Contractor shall not be responsible to the Subcontractor for any failure to perform its obligations under this agreement where there is a corresponding failure by the Authority to perform its obligations under the Main Contract, provided that the Main Contractor takes all reasonable steps to pursue its rights under the Main Contract.

9. TERMINATION

9.1 The Main Contractor may terminate this Agreement on SIX (6) months written notice.

9.2 Without prejudice to any rights that have accrued under this agreement or any of its rights or remedies, either party may terminate this agreement in whole or in part with immediate effect by giving written notice to the other party if:

(a) the other party fails to pay any amount due under this agreement on the due date for payment and remains in default not less than 30 days after being notified in writing to make such payment;

(b) the other party commits a material breach of any term of this agreement (other than failure to pay any amounts due under this agreement) and (if such breach is remediable) fails to remedy that breach within a period of 30 days after being notified [in writing] to do so;

(c) the other party repeatedly breaches any of the terms of this agreement;

(d) the Main Contractor reasonably considers that the Subcontractor has caused it, or may cause it, to be in breach of any term of the Main Contract;

(e) the Main Contractor reasonably considers that any conduct of Subcontractor would be grounds for termination by the Authority were it to be conduct of the Main Contractor, whether the Authority is on notice of such conduct or not and whether the Authority is proposing to impose any sanction or termination the Main Contract or not;

(f) the other party suspends, or threatens to suspend, payment of its debts or is unable to pay its debts as they fall due or admits inability to pay its debts or is deemed unable to pay its debts within the meaning of section 123 of the Insolvency Act 1986;

(g) the other party commences negotiations with all or any class of its creditors with a view to rescheduling any of its debts, or makes a proposal for or enters into any compromise or arrangement with its creditors;

(h) a petition is filed, a notice is given, a resolution is passed, or an order is made, for or in connection with the winding up of that other party (being a company);

(i) an application is made to court, or an order is made, for the appointment of an administrator, or if a notice of intention to appoint an administrator is given or if an administrator is appointed over the other party (being a company);

(j) the holder of a qualifying floating charge over the assets of that other party (being a company) has become entitled to appoint or has appointed an administrative receiver;

(k) a person becomes entitled to appoint a receiver over the assets of the other party or a receiver is appointed over the assets of the other party;

(l) a creditor or encumbrancer of the other party attaches or takes possession of, or a distress, execution, sequestration or other such process is levied or enforced on or sued against, the whole or any part of the other party's assets and such attachment or process is not discharged within 14 days;

(m) any event occurs, or proceeding is taken, with respect to the other party in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events mentioned in clause 9.2(f) to clause 9.2(l) (inclusive);

(n) the other party suspends or ceases, or threatens to suspend or cease, carrying on all or a substantial part of its business;

(o) there is a change of control of the other party (within the meaning of section 1124 of the Corporation Tax Act 2010); or

(p) any warranty given in this agreement is found to be untrue or misleading.

9.3 The Main Contractor may terminate this agreement immediately by notice in writing if the Subcontractor is in breach of its compliance obligations under clause 7.

10. COUNTERPARTS

10.1 This agreement may be executed in any number of counterparts, each of which when executed shall constitute a duplicate original, but all the counterparts shall together constitute the one agreement.

11. THIRD PARTY RIGHTS

No one other than a party to this agreement, their successors and permitted assignees, shall have any right to enforce any of its terms.

12. NO PARTNERSHIP OR AGENCY

12.1 Nothing in this agreement is intended to, or shall be deemed to, establish any partnership or joint venture between any of the parties, constitute any party the agent of another party, or authorise any party to make or enter into any commitments for or on behalf of any other party.

12.2 Each party confirms it is acting on its own behalf and not for the benefit of any other person.

13. CONFLICT

13.1 If there is any conflict between Schedule 1 and the other clauses and Schedules of this agreement, the other clauses and schedules of this agreement shall take precedence.

14. GOVERNING LAW

This agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by and construed in accordance with the law of England and Wales.

15. JURISDICTION

Each party irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to settle any dispute or claim arising out of or in connection with this agreement or its subject matter or formation (including non-contractual disputes or claims).

This agreement has been entered into on the date stated at the beginning of it.

Signed by Dominic Mckenna .....
for and on behalf of
Lancashire & South Cumbria NHS
Foundation Trust

Signed by [ ] .....
for and on behalf of XXXXX add
name of pharmacy here

Schedule 1 - Main Contract

1.1 Impact of Smoking

Lancashire County Council has a core purpose in ensuring that the services it provides make the most difference in reducing poverty, discrimination and inequality and in improving the quality of life for local people. Lancashire county is divided into three locality areas – North, East and Central:

- North Lancashire is comprised of Lancaster, Fylde and Wyre
- East Lancashire is comprised of Ribble Valley, Pendle, Burnley, Hyndburn and Rossendale.
- Central Lancashire is comprised of Preston, South Ribble, Chorley and West Lancashire.

Service delivery will be in line with this model. The Authority has a statutory duty to provide stop smoking services and submit service data to the Health and Social Care Information Centre on behalf of the Department of Health (DH) on a quarterly basis.

Tobacco smoking is the single largest preventable cause of ill health, premature death and inequalities in the communities we serve, killing over 79,000 people each year in England and 1,673 adults aged 35 years and over in Lancashire alone[1,2]. This is greater than the total number of deaths from alcohol, obesity, illegal drugs, murder, suicide, road traffic accidents and HIV infection combined[1,2].

Smoking rates remain higher in Lancashire than England as a whole in adults[3] (Table 1; 19.8% vs 18.4%), pregnant women[4] (Table 2; 16.8% vs 12.0%) and young people[5,6] (11% vs 8%). Smoking also disproportionately affects those disadvantaged by poverty and is a major contributor to health inequalities, accounting for half of the difference in life expectancy between social classes I and V[7,8]. Nationally, adults in routine and manual occupations are twice as likely to smoke as those in managerial and professional occupations (30% vs 13.8% respectively)[9]. People on low incomes start smoking at a younger age and are more heavily addicted, spending up to 15% of their total weekly income on tobacco[10]. In Lancashire County, around a third of our routine and manual workers currently smoke (30.4%)[11] and therefore tobacco has a greater impact on disadvantaged families in this area..

Smoking rates are also higher among people living with a mental health condition (33%), alcohol dependence (46%) and drug dependence (69%)[12]. However, over two-thirds of smokers want to quit and welcome support to do so[13].

Table 1: Estimated Number of Smokers Aged 16 years and above by Stop Smoking Service Area in Lancashire County
Source: Public Health Outcomes Framework, November 2014

Stop Smoking Service Area	% Smoking Prevalence	Total Population 16+ Years	Estimated Number of Smokers	10% Estimated Number of Smokers*	5% Estimated Number of Smokers*
North Lancashire	18.12%	272,738	49,429	4,943	2,471
East Lancashire	20.58%	307,661	63,306	6,331	3,165

Central Lancashire	21.77%	292,832	63,739	6,374	3,187
West Lancashire**	16.55%	91,694	15,178	1,518	759
Lancashire Total	**19.86%**	**964,925**	**191,652**	**19,166**	**9,582**

* National guidance stipulates stop smoking services should successfully treat 5% of total smoking population, with a minimum 50% quit rate, requires 10% of total smoking population to access service[12]

** West Lancashire is included in the Central locality

Table 2: Smoking status at Time of Delivery (SATOD) 2013/14 by Stop Smoking Service Area in Lancashire County

Source: NHS Information Centre for Health and Social Care (2014). *Statistics on women's smoking status at time of delivery: England.* http://www.ic.nhs.uk/statistics-and-data-collections/health-and-lifestyles/smoking

Stop Smoking Service Area	% Smoking Prevalence	Total Number of Maternities	Number Women Smoking at Delivery	10% Number Women Smoking at Delivery
North Lancashire	15.7%	2,835	446	45
East Lancashire	18.0%	4,418	797	80
Central Lancashire	16.8%	4,279	720	72
West Lancashire*	14.4%	989	142	14
Lancashire Total	**16.8%**	**12,521**	**2,105**	**211**

* West Lancashire is included in the Central locality

Tobacco use is evolving and now involves other products in addition to traditional stick cigarettes or hand rolled tobacco, such as shisha and smokeless niche tobacco e.g. paan, gutkha and naswar. Shisha tobacco, although not a new product either worldwide or in the United Kingdom (UK), has also become more prominent in the last ten to fifteen years. In many communities in Lancashire shisha tobacco could be regarded as the product of choice. In recent years, Lancashire has experienced an upsurge in the popularity of commercial shisha bars and lounges among the youth population[14], which serve as safe, alcohol-free environments to socialise with the opposite sex[15]. Locally, there are currently three licensed premises operating in Preston, although potentially there could be many more functioning illegally underground. Data from a 2015 Trading Standards Survey with 2,185 young people across Lancashire has demonstrated that locally one in six (17%) of 14-17 year olds have tried or experimented with shisha smoking[6].

The total cost of smoking to society in Lancashire, including lost productivity, sick days, illness and death, social care, house fires and dealing with tobacco litter is estimated to be £291.7 million each year[16]. Reducing health inequalities resulting from smoking and protecting successive generations of young people from the harm done by tobacco therefore remains a public health priority in Lancashire.

1.2 Impact of Second-hand Smoke

Tobacco smoke contains over 4,000 chemicals, 69 of which are carcinogenic. Tobacco smoke not only damages a smoker's health but also the health of the people around them. Breathing

other people's smoke is called passive or second-hand smoking (SHS). The World Health Organisation (WHO) has listed SHS as a human carcinogen to which there is no safe level of exposure[17].

Long term exposure to SHS increases a non-smoker's risk of developing heart disease and lung cancer by a quarter and stroke by three-quarters[18,19]. Children are especially at risk from the effects of SHS because they have smaller vessels and their organs are still developing. Therefore they breathe faster and breathe in more toxic chemicals than adults[20].

Nationally, over a third (37%) of all children live in a house with at least one person who smokes[20]. Children exposed to SHS are at increased risk of bronchitis, asthma symptoms, middle ear infections (glue ear), meningitis and sudden infant death syndrome (cot death)[20]. A report conducted by the Royal College of Physicians estimates that second-hand smoke annually causes:

- 20,500 new cases of lower respiratory tract infection in children aged two years and under
- 121,400 new cases of middle ear infections in children of all ages
- 22,600 new cases of wheeze and asthma in children
- At least 200 new cases of bacterial meningitis

Based on these national figures[20], it is estimated that there are 3,057 additional incidents of childhood diseases each year within Lancashire, directly attributable to SHS [21]:

- 360 new cases of lower respiratory tract infection in children under three years old
- 2,267 new cases of middle ear infections in children of all ages
- 419 new cases of wheeze and asthma in children
- At least 11 new cases of bacterial meningitis

The effect of increased illnesses for children leads to loss of school days and decreased attendance leads to lower attainment[22]. In addition, children learn their behaviour from adults and those who live with smokers are far more likely to become smokers themselves, which perpetuates cycles of health inequalities and deprivation[8,23,24]. The financial impact is also significant. Locally, it is estimated that exposure of adults and children to SHS in Lancashire, costs the National Health Service (NHS) £5 million to treat every year[16].

1.3 Lancashire Tobacco Control Strategy

Further to this, a comprehensive Tobacco Control Strategy for Lancashire has been developed to reduce smoking prevalence rates in adults, pregnant women and young people in line with the national Public Health Outcomes targets to:

- Reduce adult (aged 18 or over) smoking prevalence to 18.5% or less by the end of 2015
- Reduce rates of regular smoking among 15 year olds to 12% or less by the end of 2015
- Reduce rates of smoking throughout pregnancy to 11% or less by the end of 2015

The strategy mirrors the six aims of the government's Healthy Lives, Healthy People – A Tobacco Control Plan for England[25], in addition to three local ones (7-9):

1. Stop the promotion of tobacco
2. Make tobacco less affordable
3. Effectively regulate tobacco products
4. Help tobacco users to quit

5. Stop exposure to second-hand smoke
6. Effectively communicate for tobacco control
7. Protect tobacco control policy from industry influence
8. Reduce health inequalities
9. Ensure tobacco control is prioritised

One of the key commitments of the strategy is to encourage more smokers to quit by using the most effective forms of support, through local stop smoking services. There is strong evidence for the provision of smoking cessation support as a key part of tobacco control and health inequalities policy at national level[26,27]. Evidence based Stop Smoking Services are highly effective both clinically and in terms of cost[12,28-30], with smokers four times more likely to quit using these services than going it alone.

1. London Health Observatory (2011). *Local Tobacco Control Profiles for England – Public Health Observatories in England Nov 2011*. http://www.lho.org.uk/Download/Public/17712/1/Tartan%20Rug_FINAL_Nov2011%20v2.pdf
2. The Information Centre for Health and Social Care (2013). *Statistics on Smoking: England, 2013.* http://www.hscic.gov.uk/catalogue/PUB11454/smok-eng-2013-rep.pdf
3. Public Health Outcomes Framework (2014) *Smoking Prevalence 2013.* PHOF, November 2014.
4. NHS Information Centre for Health and Social Care (2014). *Statistics on women's smoking status at time of delivery: England.* http://www.ic.nhs.uk/statistics-and-data-collections/health-and-lifestyles/smoking
5. The Information Centre for Health and Social Care (2014) *Smoking, drinking and drug use among young people in England in 2013*.
6. Trading Standards (2015). *Young Persons Alcohol and Tobacco Survey 2013, Lancashire Results*. TSNW, 2015.
7. Wanless D (2004) *Securing good health for the whole population.* London: TSO
8. Marmot et al (2010) *Fair Society, Healthy Lives: strategic review of health inequalities in England post 2010.* Marmot Review Secretariat London.
9. Office for National Statistics (2014) Integrated household survey, self-reported smoking prevalence, persons, aged 18+, 2011-12.
10. Office for National Statistics (2010) *General Lifestyle Survey 2009.*
11. Public Health England (2014) *Local Tobacco Control Profile: Lancashire.* www.tobaccoprofiles.info
12. National Centre for Smoking Cessation and Training (2014). *Local Stop Smoking Services, Service and Delivery Guidance 2014*. London: NCSCT.
13. Smoking Toolkit Study http://www.smokinginengland.info
14. Measham F, O'Brien K and Turnbull G (2014).*Emerging Drug Trends in Lancashire: Tobacco use, gender, ethnicity & teenage smoking: An exploratory mixed methods study*. *Phase Five Report*. School of Applied Social Sciences, Durham University, UK.
15. Molloy E, Morris D (2013) *Reducing the Harms Caused by Illicit Tobacco.* Preston City Council and Lancashire Teaching Hospitals NHS Foundation Trust, November 2013.
16. Action on Smoking and Health (ASH) (2014) *The Local Cost of Tobacco, ASH Ready Reckoner 2014 Update.*
17. World Health Organisation (2005). *WHO Framework Convention on Tobacco Control* https://www.who.int/fctc/text_download/en/index.html
18. Scientific Committee on Tobacco and Health Great Britain (SCOTH) (1998). *Report of the Scientific Committee on Tobacco and Health.* London: TSO 1998.
19. Scientific Committee on Tobacco and Health Great Britain (SCOTH) (2004). *Secondhand Smoke: Review of evidence since 1998.* Scientific Committee on Tobacco and Health Great Britain (SCOTH) , November 2004.
20. Royal College of Physicians (2010). *Passive smoking and children.* A report by the Tobacco Advisory Group. London: RCP, 2010.
21. Tobacco Free Futures (2012). *Locality Tobacco Briefings September 2012: Lancashire.* TFF 2012.
22. Gilliland FD et al (2003). Environmental Tobacco Smoke and Absenteeism Related to Respiratory Illnesses in Schoolchildren. *Am J Epidemiol* **157**(10):861-869.
23. Loureiro M, Sanz-de-Galdeano A, Vuri D (2010). Smoking Habits: Like Father, Like Son, Like Mother, Like Daughter? *Oxford Bulletin of Economics and Statistics* **72**(3):717-43.
24. Tobacco Advisory Group of the Royal College of Physicians (2000) *Nicotine Addiction in Britain.* London: RCP.
25. Department of Health (2011). *Healthy Lives, Healthy People: A Tobacco Control Plan for England.* www.dh.gov.uk/publications
26. Department of Health (2008) *Excellence in tobacco control: 10 high impact changes to achieve tobacco control*. DH
27. West R. et al (2000) *Smoking cessation guidelines for health professionals: an update.* Thorax 55(2):987-99
28. Department of Health (2011) *Local Stop Smoking Services: Service Delivery and Monitoring Guidance 2011/12.*London: DH
29. Department of Health (2012). *Local Stop Smoking Services: key updates to the 2011/12 service delivery & monitoring guidance for 2011/12*. London: DH
30. Local Government Association (2015). *Tackling Tobacco and Nicotine Dependency*. London: LGA.

The Tobacco and Nicotine Addiction Treatment Service will contribute to the following outcomes:

Expected Outcomes

- A reduction in smoking prevalence and the number of tobacco users across Lancashire
- A reduction in health inequalities by ensuring that the service is delivered in line with the Marmot recommendations[1] and aimed at the following target populations:
  - Routine and manual workers, long-term unemployed and never worked groups.
  - Pregnant women and their partners.
  - People residing in disadvantaged areas.
  - Black Asian Minority Ethnic communities.
  - People with a diagnosed mental health condition.

[1]Marmot et al (2010) *Fair Society, Healthy Lives: strategic review of health inequalities in England post 2010.* Marmot Review Secretariat London.

  - People with long-term conditions, such as chronic obstructive pulmonary disease (COPD), diabetes, cancer, coronary heart disease (CHD) and asthma.
  - People within substance misuse services.

- A reduction in the risk of developing smoking related conditions and the deterioration of existing conditions, including COPD;
- A reduction in exposure to second-hand smoke and associated risks
- A decrease in the financial costs of smoking
- Improved service user satisfaction;
- Improved co-ordination and access to services;
- Improved information about tobacco and nicotine cessation support and interventions;
- Increased number of frontline staff engaging with the Tobacco and Nicotine Addiction Treatment Service and referring or delivering tobacco and nicotine cessation interventions;
- Integration into the wider tobacco control agenda.
- Integration into health and wellbeing lifestyle programmes

The service contributes to the following Marmot principles[1], Public Health Outcomes Framework and Lancashire County Council Health and Wellbeing shifts:

Marmot Principles

- Give every child the best start in life
- Enable all children, young people and adults to maximise their capabilities and have control over their lives
- Create fair employment and good work for all
- Ensure healthy standard of living for all
- Create and develop healthy and sustainable places and communities
- Strengthen the role and impact of ill health prevention

Public Health Framework Outcomes

- Smoking status at time of delivery (2.3)
- Smoking prevalence – 15 year olds (2.9)
- Smoking prevalence – adult (over 18s) (2.14)
- Low birth weight of term babies (2.1)
- Infant mortality (4.1)
- Mortality from causes considered preventable (4.3)
- Mortality from all cardiovascular diseases (including heart disease and stroke) (4.4)
- Mortality from cancer (4.5)
- Mortality from respiratory diseases (4.7)
- Excess under 75 mortality in adults with serious mental illness (4.9)
- Sickness absence rate (1.9)

Lancashire County Council Health and Wellbeing Shifts

- Shift resources towards interventions that prevent ill health and reduce demand for hospital and residential services
- Promote and support greater individual self-care and responsibility
- Commit to delivering accessible services within communities
- Make joint working the default option
- Work to narrow the gap in health and wellbeing and its determinants

Aims

The Tobacco and Nicotine Addiction Treatment Service will:

- Provide comprehensive, consistent and evidence-based smoking cessation, tobacco and nicotine addiction treatment for Lancashire residents who wish to quit, which is equitable and accessible and which meets local authority targets and aspirations.
- Target provision to geographical areas of high deprivation and to priority groups in order to address the Marmot recommendations[2] and reduce health inequalities.
- Build capacity to enable it to respond to the needs of the population in different parts of the Local Authority area, and engage with and support the wider tobacco control agenda.
- Raise awareness of the harms associated with SHS, promote the principle of a smokefree home and car and facilitate pledges within the Lancashire community.
- Contribute towards a reduction in levels of smoking during pregnancy and post-partum.

Objectives

- Provide tobacco and nicotine users with flexible and quick access to evidence-based and effective cessation support;
- Achieve smoking cessation and associated targets;
- Engage with tobacco and nicotine users to provide services that are responsive and needs led;
- Ensure the service provides optimum reach;
- Achieve optimal success rates for interventions provided;
- Provide leadership, management and coordination between the Tobacco and Nicotine Addiction Treatment Service and community providers e.g. pharmacies;
- Engage effectively with primary and secondary care services to provide evidence based interventions;
- Provide accurate and timely data on smoking status for the Local Authority;
- Establishment of comprehensive communications and marketing strategy to raise awareness of the harms associated with tobacco use and second-hand smoke, awareness of cessation support and the smokefree homes programme through national and local promotional and social marketing activities;
- Development and delivery of a comprehensive training programme to engage with key partners to provide cessation and smokefree homes support at all levels.
- Ensure the provision of appropriate smokefree homes, smoking and nicotine cessation resources to key partners and develop capacity to deliver smoking and nicotine cessation and smokefree homes interventions across community, health and workplace settings;
- Deliver a smokefree pregnancy scheme to pregnant women and their supportive partners;
- Work in partnership with the Local Authority, health, Voluntary, Community and Faith Sector (VCFS) sector and other stakeholders to support the wider tobacco control agenda;
- Work in partnership with other healthy lifestyle programmes;
- Develop and maintain systems to monitor services and provide timely and accurate data as required nationally (e.g. Health and Social Care Information Centre) and locally;
- Establish systems for regular service user feedback to inform service improvements and conduct regular audits;
- Provide regular reports and progress updates as required by the Authority;
- On occasions, supporting the wider wellbeing, prevention and early help directorate;
- Reach out to the wider community with use of social media.

[2] Marmot et al (2010) *Fair Society, Healthy Lives: strategic review of health inequalities in England post 2010.* Marmot Review Secretariat London.

Schedule 2 - Scope of Work

Pharmacy Criteria

This service may be provided by any authorised community pharmacy within Lancashire, subject to the following:

- The pharmacy contractor must agree to participate in all parts of the service. This agreement will be documented in the form of a Service Level Agreement signed by the contractor or the representative of the contractor. (Appendix 3)
- The pharmacy must meet the standards required to deliver advanced services.
- A standard operating procedure (SOP) that clearly defines the roles and responsibilities of relevant staff must be produced and followed for each individual pharmacy.
- A suitably trained member of the pharmacy team may undertake the consultation provided they adhere to the SOP and refer to the pharmacist as appropriate. Overall responsibility and accountability will remain with the pharmacist in charge.
- An accredited pharmacist must be present and accountable for 75% of opening hours, except for annual leave and sick leave, when a locum (accredited or not accredited) may temporarily continue accountability of the service.

Pharmacist and Pharmacy Staff Accreditation

- **Pharmacist Training & Qualifications**

Pharmacists involved in the provision and/or accountability of this service must have completed the 'Stop Smoking – very brief advice' e-package (NCSCT version) distance learning package available from the Centre for Postgraduate Pharmaceutical Education (CPPE) website: http://www.cppe.ac.uk

- **Pharmacy Technician Training & Qualifications**

Qualified Dispensing Technicians (NVQ level 3) must have received training by the Stop Smoking Service to supply NRT under the scheme. Registered Technicians are also encouraged to complete the CPPE package.

- **Sign Up and Termination**

All pharmacists and pharmacies must agree to the terms of service contained within this service specification.

Participating authorised pharmacies may withdraw from the scheme at any time. Lancashire County Council may also terminate provision from a pharmacy. Any such intention must be made in writing to the same individual identified on the Enhanced Service agreement form. A notice of 28 days applies.

If pharmacies withdraw from the scheme, then the accredited pharmacist may continue to provide the service from other authorised pharmacy premises located within Lancashire

Changes of ownership will require reapplication to provide the service.

Changes to pharmacy staff (e.g. new manager or regular locum) who are not already accredited will require accreditation to continue provision of the service.

Service model

The process can be summarised as follows:

- Clients of the stop smoking service who have committed to a target stop date and wish to use NRT, and who are assessed as suitable, are issued with a voucher by their smoking cessation advisor.
- The standard duration of treatment on the Pharmacy Enhanced Service NRT voucher scheme is 12 weeks per cessation attempt.
- Initial supply of the NRT should be sufficient to last up to a maximum of 2 weeks after the target stop date. A second voucher should only be issued if the smoker demonstrates a continuing attempt to stop smoking. Best practice dictates that during the first four weeks of the quit attempt, behavioural support should be offered on a weekly basis. The NRT voucher will usually cover one or two weeks' supply of NRT. In exceptional circumstances, up to four weeks supply of NRT may be issued on a single voucher.
- Where circumstances dictate e.g. in high level of dependence, up to two forms of NRT may be combined on the same voucher, in accordance with the service specification. Usually this will be a patch plus some form of oral treatment.
- Subsequent vouchers will only be issued where the client demonstrates on re-assessment that the quit attempt is continuing.
- The client takes the voucher to a participating pharmacy and exchanges this for a supply of NRT. For clients who are not exempt from NHS charges, a non-refundable fee equivalent to the NHS prescription charge will be levied.
- The voucher will be valid for 14 days from the issue date.
- The pharmacist claims the cost of the product plus VAT and a professional fee of £2.62 per voucher from the Commissioning Support Unit (CSU) – via Pharmoutcomes.
- The NRT Voucher scheme may only be used to supply NRT on the NHS to persons undertaking a smoking quit attempt. Supporting persons with a long term dependency to NRT is outside the scope of the service.
- If appropriate the Stop Smoking Advisor may suggest a reducing to quit programme for up to two weeks. A quit attempt should then be made. Complete cessation must be no later than 14 weeks. The reducing to quit programme is not an appropriate method for pregnant/breastfeeding women who smoke.
- Clients requiring treatment for longer than the standard 12 week duration will be assessed on an individual basis. Adolescents between the age of 12-18 yrs, pregnant or breast feeding clients would rarely be treated for longer than the standard 12 week duration.

THE ROLE OF THE STOP SMOKING SERVICES MANAGER/DEPUTY MANAGER

The Manager/Deputy Manager has overall responsibility for use of the NRT voucher scheme within the Stop Smoking Service. This includes:

- Arrange the printing of the voucher, and co-ordinate the distribution to the local advisors.
- Compile a list of signatures of all advisors using the voucher scheme and distribute this list regularly to all participating pharmacists, at least every three months.
- Record serial numbers of voucher pads and who they have been distributed to
- Ensure ongoing competency of the advisor in use of NRT and the voucher scheme.
- Provide up-to-date information to advisors and participating pharmacists on the use of NRT and the voucher scheme, as required.

ROLE OF THE STOP SMOKING ADVISOR

- Assess client suitability for NRT in accordance with NICE and Department of Health Guidelines The choice of product(s) must be consistent with the Lancashire NRT Formulary (Appendix 1).
- Vouchers will normally be issued for 1-2 weeks supply. Up to 4 weeks supply can be issued once the client has been co-verified as a successful quitter (at 4 weeks).
- Complete part one of the voucher and inform clients of participating pharmacies.
- Indicate on the voucher whether one product or two products are recommended by ticking the relevant box.
- Ensure the date of issue is completed on the top copy. Encourage the client to obtain treatment within 7 days, and to take proof of eligibility for free prescriptions.
- Retain the bottom (yellow) copy of the voucher within the client's record. This must be stored safely and be available for up to 8 years.
- Vouchers should not be collected by persons other than the client. If this poses particular problems for an individual, they should speak with the Stop Smoking Service Manager/Deputy Manager.
- Vouchers cannot be issued after 14 weeks of treatment per quit attempt.
- Forward any spoiled vouchers to the SSS.
- Client is to be advised to discuss product preferences e.g. flavour of gum with the supplying pharmacist.
- Ask the client to present the top (white) copy of the voucher and the treatment card at the pharmacy.

ROLE OF THE PHARMACIST

All pharmacists should ensure that they have signed up to the Stop Smoking Services NRT Voucher Scheme Service Specification, before supplying NRT under the voucher scheme. It is expected that all new pharmacy contractors complete the 'Stop Smoking – very brief advice' e-package (NCSCT version) e-package (http://www.cppe.ac.uk) and undertake the local Stop Smoking Service training session within 6 months of starting to supply NRT under the scheme.

If the pharmacist has any concerns or queries over the NRT order on the voucher, they should discuss this with the issuing stop smoking service adviser before supply.

- The Pharmacy Contractor will ensure that Pharmacists and staff make the supply of NRT in accordance with the service specification and produce a standard operating procedure for use in the pharmacy (Appendix 2).
- The Pharmacy Contractor will ensure the service is covered by their indemnity insurance.
- At least one representative from the Pharmacy Contractor must attend the Stop Smoking Service training session, and arrange for the information to be disseminated to pharmacy staff.
- The Pharmacy Contractor will display a notice indicating the availability of treatment through the NRT scheme.
- In taking the professional responsibility for the supply of the NRT, the pharmacist should assure him/herself that the NRT therapy is being supplied safely paying particular attention to the client's medical conditions and concurrent medication (including possible side effects, drug interactions and contra-indications).
- Ensure adequate stocks of the NRT products available on the voucher scheme are maintained within the pharmacy.
- All clients should present with a voucher and treatment card. However, they may not bring their treatment card with them to the pharmacy. In such a case, the client may still receive a supply of NRT providing they have a valid voucher. If a treatment card is presented, it should tally with the voucher. You should document anything out of the ordinary and report to the appropriate service manager.
- Ensure the voucher has been completed satisfactorily. If any details are absent contact the Stop Smoking Service.

- Check that the voucher has not expired. Vouchers are valid for 14 days from the date written on the voucher. If the voucher has expired, advise the client to contact their stop smoking service advisor.
- Ensure the NRT product requested is appropriate for use by the client in accordance with the product licence.
- Discuss any particular client product preferences e.g. flavour of NRT gum or type of patch.
- Take professional responsibility for the supply of the NRT. The voucher is not a prescription. It is a means of supplying NRT on the NHS. The pharmacist is professionally accountable for the supply. The pharmacist retains professional discretion to judge the suitability of the NRT product recommended and change the product if deemed necessary. If the pharmacist has a query, they must contact the stop smoking service advisor. If an amendment to the voucher is necessary, the pharmacist should clearly annotate the voucher with the amendment, signing both copies of the voucher.
- Make an entry on the PMR and label the NRT supply in accordance with RPSGB Labelling Guidelines (now called the GPhC).
- In permanent ink, mark on the box of NRT "Supplied on the NHS"
- Complete the relevant section on the voucher. Fill in the pharmacist's name and stamp with the pharmacy details.
- Retain the copy of the voucher. This must be made available to the CSU at a later date as part of an audit trail/for audit purposes should this be required. They must be stored safely for 2 years and thereafter confidentially shred.
- Complete the voucher details on the PharmOutcomes database and submit to the CSU within the calendar month if possible but no longer than 3 month's duration from issuing of NRT. Reimbursement may not take place if outside of this period.

VOUCHERS

A voucher approved by the Lancashire Tobacco and Nicotine Addiction Treatment Service must be used. This will be produced in duplicate (white top copy, yellow bottom copy) in A5 size.

THE PROCEDURE FOR USING THE VOUCHER

The stop smoking service advisor completes the relevant sections of the voucher. Amendments should not be made apart from indicating client preference for product flavour. If any alteration to the voucher is required, this must be clearly indicated and the amendments signed on all voucher copies. If necessary, where there is scope for ambiguity, the instruction should be written out in full.

The stop smoking service advisor retains the bottom (yellow) copy of the voucher for the records and provides the client with the top two copies to take to a participating pharmacy.

Where clients are exempt from prescription charges, they must tick the appropriate box on the voucher under exemption categories and sign the declaration.

The pharmacist must check their proof of exemption.

If proof of exemption is not seen, place a cross on the back of the voucher and endorse 'proof of exemption not seen'.

Where the client is not exempt from prescription charges they must complete the declaration. Collect any NHS fees (equivalent to the standard prescription charge) where appropriate in accordance with current Department of Health policy i.e. one charge per item unless it is for different strengths of the same formulation. A till receipt should be issued for the charge made,

which should be the current prescription charge. If a client is awaiting an exemption certificate do not issue an FP57 as the NRT voucher is not a prescription and therefore this would not be appropriate. If the client later presents with a valid exemption certificate a refund should be made providing the till receipt is also presented. The amount of the refund should be claimed back from the CSU. The till receipt should be submitted with the exemption certificate number clearly indicated.

The pharmacist completes the voucher with the Pharmacist's name and pharmacy stamp, supplying the NRT product for the client in return for the voucher. The pharmacist keeps the top (white) copy of the voucher and submits the details to the CSU via PharmOutcomes.

REIMBURSEMENT TO PHARMACISTS

Pharmacists will be reimbursed with the current Drug Tariff price for the NRT supplied plus VAT, plus a professional fee of £2.62 per voucher. Any NRT product requested and supplied on the voucher should be in accordance with the NRT voucher scheme formulary as presented in Appendix 1. The reimbursement prices for the NRT products on the formulary will be updated quarterly.

All enquiries regarding fee payment need to be directed to the CSU:
Contracts Management Team
NHS Midlands and Lancashire Commissioning Support Unit
Jubilee House
Leyland
Lancashire
PR26 6TR Tel: 01772 214149 Email: enhancedserviceslcsu@nhs.net

ROLE OF THE CSU

Check that the voucher details have been completed satisfactorily on PharmOutcomes. Raise any incomplete vouchers with the pharmacy.

Arrange reimbursement to pharmacies.

Produce quarterly budget statements and reports to support the monitoring of the North, East and Central schemes for Lancashire Tobacco and Nicotine Addiction Treatment Service and Lancashire County Council.

FINANCIAL ARRANGMENTS WITH THE CSU

A financial system has been set up in order to calculate and make appropriate payments to pharmacies. Ordinarily we will only pay claims up to three months after the claim period. The following data will be collected by the CSU:

- Supply date
- Patient name, date of birth and address, including postcode
- Pharmacist's and pharmacy details
- Voucher issuing advisor details
- Number of voucher
- Reimbursement cost of the NRT supplied (Plus VAT as appropriate)
- Type of NRT supplied
- Patient exemption status

Reports regarding the number of vouchers and NRT products redeemed will be provided to the stop smoking services and Lancashire County Council on a quarterly basis.

FRAUD AND AUDIT PROCEDURES

All necessary steps to eliminate the possibilities for fraud at any stage in the voucher scheme will be taken. In summary they will include:

- Ensuring the voucher issued to clients who are entitled to free prescriptions can identify their exemption category in section 3 of the voucher.
- Carrying out the necessary checks, including post-supply checks on clients who have no evidence of their entitlement to free prescriptions.
- Ensuring that the products are supplied as indicated on the voucher and that the number of vouchers is consistent with the number of clients using the service.
- Establishing an audit trail for the vouchers so that they can be tracked from their point of issue to their submission to the CSU.

The voucher has been specifically designed to reduce the possibility of fraud and enables advisors to easily identify clients eligible to receive NRT. The Lancashire Tobacco and Nicotine Addiction Treatment Service manager/deputy manager will be responsible for arranging printing of the A5 copies of the voucher in duplicate and to distribute these appropriately to the advisors. Each copy of the voucher will be in a different colour and the copy carbonated. Each voucher will have a unique serial number so that it can be tracked and audited.

Other aspects of the use of the NRT voucher scheme will be audited periodically in agreement with Lancashire Tobacco and Nicotine Addiction Treatment Service and community pharmacists (via the Local Pharmaceutical Committee).

THE PENALTY CHARGE

The supply of the NRT free of charge falls within the scope of the penalty charge introduced from November 1999. The penalty charge is a civil fine, and is payable in addition to the recovery of the item. Payment can be pursued by civil recovery action if necessary.

Where clients have claimed the free NRT incorrectly or fraudulently, the cost of the item should be recovered and the penalty charge will apply. Guidance on the penalty charge administration will be issued by the Department of Health.

OTHER COUNTER FRAUD MEASURES

The CSU will need to be able to satisfy themselves that products are being supplied as indicated on the voucher, that the NRT provided is supplied in accordance with the clinical need of the client, and that the number of vouchers is consistent with the number of clients using the service.

AUDIT TRAIL

The CSU has established an audit trail for the vouchers so that they can all be individually tracked from the point of issue at the pharmacy through to their submission to the CSU. A sample audit of the vouchers may be carried out.

BUSINESS CONTINUITY

The provider should ensure that sufficient staffing is available for the effective running of the scheme, including contingency planning for times of sickness, absences or any other occurrence that may jeopardise the delivery of the scheme to service users at levels sufficient to meet the performance objectives and service standards of the scheme as outlined in this agreement.

BUILDINGS AND ACCOMODATION

The provider will be responsible for sourcing buildings that have the appropriate planning permission for delivering public health services.

The service provider will be responsible for the maintenance costs of any buildings occupied for delivering services, which includes fittings, equipment, repairs and alterations. The provider will be responsible for any costs associated with the replacement of furniture, maintenance and calibration of equipment and the safe disposal of the same, and provide consumables required for the smooth operation of the building.

COMMUNICATION AND MARKETING

All costs in relation to communication and marketing will be met by the provider.

Population covered

The Pharmacy Enhanced Service NRT voucher scheme is available to any tobacco using person aged 12 years and over, registered with a G.P practice in Lancashire County. The individual must be sufficiently motivated to quit and must have received specialist stop smoking advice and support from the countywide Lancashire Tobacco and Nicotine Addiction Treatment Service.

The scheme recognises that many smokers will require multiple attempts to quit9 and therefore offers vouchers to support recurrent cessation treatments.

The scheme will be non-stigmatising and non-discriminatory, providing fair and equitable access. The service will comply with the Equality Act 2010.

The scheme will work in a way that it does not discriminate against individuals on the grounds of gender, race, disability, sexual orientation, sexual practices, gender reassignment, age, pregnancy or maternity, marriage/civil partnership or belief system and will ensure that all applicable legislation is adhered to.

The scheme is accessible to people who have had difficulties accessing support to become well, including people with mental health problems, from black and minority ethnic communities, people with sensory impairments, and people with learning disabilities or learning difficulties and people from the Gypsy / Romany / travelling communities

The scheme will meet the needs of those in training, education and employment.

Any acceptance and exclusion criteria

People working in Lancashire County but not registered with a GP within the area, are eligible to access the countywide Lancashire Tobacco and Nicotine Addiction Treatment Service for behavioural support but will need to obtain their NRT through a prescription from their own GP and not the Pharmacy Enhanced Service NRT voucher scheme.

EXCLUSION CRITERIA FOR THE NRT VOUCHER SCHEME

The supply of NRT through the voucher scheme is specifically for those smokers who are not contraindicated to NRT products. Those smokers who are contraindicated to these products will be referred back to their GP for assessment. It is anticipated that these numbers will be few. The community pharmacist operating the scheme maintains professional responsibility to ensure that the NRT supplied is safe and suitable for the patient.

The following individuals are excluded from NRT treatment through the voucher scheme:

- Individuals with known hypersensitivity to nicotine
- Individuals with renal or hepatic impairment
- Individuals with oesophagitis, gastritis, gastric or peptic ulcers should use oral NRT preparations with caution. If appropriate patches can be supplied.
- Individuals with uncontrolled hyperthyroidism should use NRT preparations with caution
- Individuals with phaeochromocytoma (tumor of cells secreting hormones which regulate heart rate and blood pressure) should use NRT preparations with caution
- Individuals under the age of 12 years
- When intervention with bupropion or varenclicine might be more appropriate
- Individuals hospitalised in the previous 4 weeks as a result of myocardial infarction, severe dysrhythmia or CVA. Any clients in this category or those with severe or unstable conditions under the care of the cardiac specialist should be referred to their G.P.
- Individuals with any contraindication to NRT

The Stop Smoking Advisor will routinely check that the client does not meet any exclusion criteria (as listed above) prior to issuing a voucher. If the client meets one or more of the exclusion criteria the Stop Smoking Advisor will complete the 'Referral to G.P Practice for Assessment of Pharmacological Intervention' form. The client will continue to receive support from the Stop Smoking Advisor, however provision of smoking cessation treatment will be at the doctor's discretion and if appropriate treatment will be supplied through a prescription.

Pharmacists providing the NRT voucher scheme maintain professional responsibility for the safe and appropriate supply of NRT to all clients. Therefore it is important that both the Stop Smoking Advisor and the Pharmacist verify that the client does not meet any exclusion criteria. When presented with a voucher and a client that meets the exclusion criteria the pharmacist should not supply the product and refer the client back to the Stop Smoking Advisor to enable the advisor to complete the 'Referral to the G.P Practice for Assessment of Pharmacological Intervention' form and make future arrangements for that client.

CRITERIA FOR INFORMING THE GP OF ATTEMPT TO QUIT

The majority of clients accessing the Lancashire Tobacco and Nicotine Addiction Treatment Service will receive NRT through the voucher scheme without their GP being notified.

However there are some instances when the Stop Smoking Advisor is required to notify the client's GP. These include:

- Client is pregnant
- Client is breastfeeding

- Client with Type I or Type II diabetes
- Clients taking warfarin, theophylline, chlorpromazine, clozapine, olanzapine or insulin11

For these specific clients the attempt to stop smoking and the use of NRT should be recorded in the patient medical records held at the G.P practice. This will be achieved by completion of the 'Information for patient records' form which is faxed to the clients GP by the Stop Smoking Advisor.

Pharmacy staff will be made aware that this requirement has been fulfilled through the annotation on the voucher under the Advisors Signature.

The client will continue to receive support and treatment from the Stop Smoking Advisor as appropriate, unless the GP informs the Stop Smoking Advisor otherwise.

Community pharmacists operating the scheme maintain professional responsibility for the safe and appropriate supply of NRT to all clients. If any criteria listed above are identified by the pharmacist and the voucher not annotated with information for patient record sent to GP, the pharmacist may supply the product providing the Stop Smoking Advisor is informed without delay and the 'Information for Patient Records form' is completed and faxed to the G.P practice by the Stop Smoking Advisor.

3.5 Interdependencies with other services

Community pharmacists will need to work in partnership with the Lancashire Tobacco and Nicotine Addiction Treatment Service, the CSU, the Local Pharmacy Committee and Lancashire County Council.

Applicable national standards e.g. NICE, Royal College

The NRT Voucher Scheme will be underpinned by the evidence base contained within the following documents:

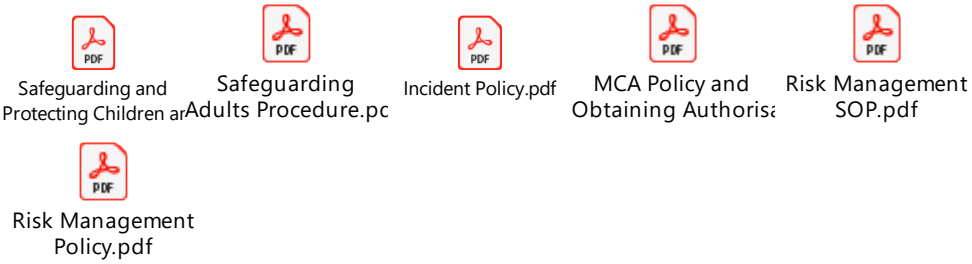
- Department of Health Local Stop Smoking Services: Service Delivery and Monitoring Guidance 2011/12.
- Department of Health Local Stop Smoking Services: key updates to the 2011/12 service delivery & monitoring guidance for 2011/12.
- National Centre for Smoking Cessation and Training (2014). Local Stop Smoking Services, Service and Delivery Guidance 2014. London: NCSCT.
- NICE Guidance on the Use of NRT and Bupropion
- NICE Guidance on the use of Varenicline
- NICE Guidance on smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual groups, pregnant women and hard to reach communities
- NICE Smokeless tobacco cessation-South Asian Communities
- NICE Guidance on tobacco: harm-reduction approaches to smoking
- All NICE Technological Appraisals for Smoking related Pharmacotherapy, including Champix

And any others which are developed.

Response times

Clients should be offered an appointment on the time, day and venue of their choice. The waiting time for an appointment should not exceed 1 week.

Safeguarding Policies and Mental Capacity Act Policies



Other Local Agreements, Policies and Procedures

A Steering Group, comprising commissioners, provider representatives and other relevant personnel as necessary will meet on a regular basis to oversee progress against the service specification, including the targets, and agree any new procedures or changes necessary.

Data sharing of individual performance will be provided to each pharmacy at the end of each quarter.

This service specification will be reviewed initially after 6 months and thereafter on an annual basis within the contract period of the service level agreement, and will take account of emerging guidance from the NHS Centre for Smoking Cessation and Training.

Sub-contractor will act as data controller and data processor.

Contract Review Meetings

Contract review meetings with the Authority will be undertaken on a quarterly basis as a minimum, but monthly for at least the first six months of contract delivery. The meetings will be held on Lancashire County Council premises and will be scheduled in advance for the full financial year. The Provider must ensure that a robust Performance Management function is in place to support effective reporting as required by the Authority for the duration of the contract. The Provider will be expected to submit all performance and activity data two weeks prior to the contract meeting.

Information Governance

Ensure compliance with, evidence and demonstrate adherence to the Data Protection Act (1998) and The General Data Protection Regulation (EU) 2016/679 (GDPR) requirements and appropriate information governance with relation to record keeping in alignment with the expectations of the Authority.

Schedule 3 - Payment

In order to receive any payment all data returns must be sent to the NHS Stop Smoking Service no later than day 42 of setting a quit date.

This will be submitted to LCFT finance department by the SSS following receipt of monitoring forms and will be paid at the end of each quarter. Please note, this is always 3 months behind due to the collection of data being submitted e.g Q4 payment Jan – March will be paid into agreed account in June .

Payment will not be made for any of the following:-

1) If no quit date is set and 4 week outcome is not completed i.e. Quit, Not quit or lost to follow up (this must also include the date of last cigarette.)

2) Spontaneous quit (e.g. if client attends and has already quit smoking).

3) For any incomplete monitoring forms or consultation forms.

4) For any late returns of data (i.e. any data out of the 26 – 42 day period (from the client setting a quit date.)

Basis of Contract	Unit of Measurement	Price	Expected Annual Contracted Value
Cost per case	Smokers setting a quit date who are successfully quit at 4 weeks capped at 50 quits per annum any amount over 50 quits achieved to be reviewed by stop smoking service	Client achieves 4 week quit (CO Verified) = £80.00 Client achieves 4 week quit (Self Report) = £45.00	**Total payment** **£80 on a successful 4 week CO verified quitter** **£45 for self-reported quit**
Bonus payments	50 x 4 week quits co verified		**£250-00**

Indicative Activity Plan

Activity Performance Indicators	***Threshold***	***Method of measurement***	***Consequence of breach***	***Report Due***
Assist Specialist Service to achieve 3,165 East,3,187 Central, 2,471 North and 759 West validated smoking quitters in 2017/18	**East 3,165 Central 3,187 North 2,471 West 759**	Quarterly returns	Service review to identify actions to improve performance. Possible withdrawal of contract.	Quarterly
Assist Specialist Service to achieve pregnant women to be	**East 80 Central 86 North 45**	Quarterly returns	Service review meeting to identify actions to improve performance	Quarterly

successfully stopped smoking at 4 weeks				
Assist Specialist Service to achieve at least 6% quits to come from BME groups	N/A	Quarterly returns	Service review meeting to identify actions to improve performance	Quarterly
Assist Specialist Service to achieve at least 50% of smoking quits to come from routine and manual workers, long-term unemployed and never worked groups	N/A	Quarterly returns	Service review meeting to identify actions to improve performance	Quarterly
The service should achieve a success rate for 4 week smoking quitters of between 35 – 70%	N/A	Quarterly returns	Service review meeting to identify actions to improve performance	Quarterly
The service should aim to achieve a CO validation rate of 85% of reported 4 week quits	N/A	Quarterly returns	Service review meeting to identify actions to improve performance	Quarterly
Assist Specialist Service to achieve at least 50% of quits pledge to adopt a smokefree home and car	N/A	Quarterly returns	Service review meeting to identify actions to improve performance	Quarterly
Improve productivity	The lost to follow up for smokers at 4 week quit date should be less than 20%	Quarterly returns	Service review meeting to identify actions to improve performance	Quarterly

Activity Performance Indicators	***Threshold***	***Method of measurement***	***Consequence of breach***	***Report Due***

Number of smokers accessing the Intermediate Stop Smoking Service who are successfully quit smoking at 4 weeks	The service should aim to achieve an Indicative activity = **50 quits per year capped any over is paid at the discretion of the SSS**	Activity monitoring forms	Service review meeting to identify actions to improve performance	Quarterly
Proportion of smokers who setting a quit date who are successfully quit at 4 weeks	Minimum quit rate of 35%	Activity monitoring forms	Service review meeting to identify actions to improve performance	Quarterly

Schedule 4 - Quality Requirements

Operational Standards and National Quality Requirements

Ref	Operational Standards/National Quality Requirements	Threshold	Guidance on definition	Consequence of breach	Timing of application of consequence	Applicable Service Category
	Duty of candour	Each failure to notify the Relevant Person of a suspected or actual Notifiable Safety Incident in accordance with Regulation 20 of the 2014 Regulations	See CQC guidance on Regulation 20 at: https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour	Recovery of the cost of the episode of care, or £10,000 if the cost of the episode of care is unknown or indeterminate	Monthly	All

The Sub-Contractor must report its performance against each applicable Operational Standard and National Quality Requirement through its Service Quality Performance Report, in accordance with Schedule 6A.

Local Quality Requirements

Quality Requirement	Threshold	Method of Measurement	Consequence of breach	Timing of application of consequence	Applicable Service Specification
Expected Outcomes The Service is to assist the Specialist Stop Smoking Service to achieve the following •A reduction in smoking prevalence and the number of smokers across East and Central Lancashire • A reduction in health inequalities by ensuring that the support services are aimed at target populations: – Routine and manual workers, long-term unemployed and never worked groups – Pregnant women and their partners. – Smokers residing in disadvantaged areas. – Black and Minority Ethnic communities. – Smokers within Acute and Mental Health Trusts.					

Quality Requirement	Threshold	Method of Measurement	Consequence of breach	Timing of application of consequence	Applicable Service Specification
– Smokers within substance misuse services.					
A reduction in the risk of developing smoking related conditions, including COPD					
A reduction in exposure to secondhand smoke and associated risks					
Improved patient satisfaction					
Improved coordination and access to services					
Improved information about stop smoking support and interventions					
More frontline staff engaging with Stop Smoking Services and referring or delivering stop smoking interventions					
Integration into the wider tobacco control agenda					
All prospective clients will be contacted by the service within 2 working days of their initial enquiry. Waiting time for					

Quality Requirement	Threshold	Method of Measurement	Consequence of breach	Timing of application of consequence	Applicable Service Specification
appointments should not exceed 1 week.					
At least 80% of clients should be satisfied with the service provided. All clients withdrawing from treatment will be contacted to establish why.					
Services will be as flexible and accommodating as possible in terms of location, times of operation, language etc and will record any instance where it has not been possible to meet a clients' request for treatment.					
The quit rate should not be below 35% and the lost to follow up rate for smokers setting a 4 week quit date should be less than 20%.					
The service should aim to treat at least 10% of the local population of smokers with a higher proportion coming from wards identified as more deprived. Plan to be agreed with commissioner to identify priority wards.					

Quality Requirement	Threshold	Method of Measurement	Consequence of breach	Timing of application of consequence	Applicable Service Specification
The service should aim to achieve a CO validation rate of 85% of reported 4 week quits The service should achieve a success rate for 4 week smoking quitters of between 35 – 70%					
For 2017/18 the Provider(s) of the LCFT Lancashire Stop Smoking Service will continue to work towards meeting the following 4 week quitter targets for 2017/18 = East 3,165 Central 3,187, North 2,471 and West 759 validated quitters.					
It is expected that the service provider will be participate in regular review meetings at the invitation of the Specialist Service Manager.					

Schedule 5 - Contract Management, Reporting and Information Requirements

Report Required	Reporting Period	Format of Report	Timing and Method for delivery of Report
Performance and activity data will be shared at the end of each quarter.			

Incidents Requiring Reporting Procedure

Procedure(s) for reporting, investigating, and implementing and sharing Lessons Learned from: (1) Serious Incidents (2) Notifiable Safety Incidents (3) Other Patient Safety Incidents
As per LCFT Incident Policy and service condition 33 of NHS Standard Full Length Contract which states: SC33 Incidents Requiring Reporting 33.1 The Provider must comply with the arrangements for notification of deaths and other incidents to CQC, in accordance with CQC Regulations and Guidance (where applicable), and to any other relevant Regulatory or Supervisory Body, any NHS Body, any office or agency of the Crown, or to any other appropriate regulatory or official body in connection with Serious Incidents, or in relation to the prevention of Serious Incidents (as appropriate), in accordance with Good Practice and the Law. 33.2 The Provider must comply with the NHS Serious Incident Framework and the Never Events Policy Framework, and must report all Serious Incidents and Never Events in accordance with the requirements of those Frameworks. 33.3 The Parties must comply with their respective obligations in relation to deaths and other incidents in connection with the Services under Schedule 6C (Incidents Requiring Reporting Procedure) and under Schedule 6A (Reporting Requirements). 33.4 If a notification the Provider gives to any relevant Regulatory or Supervisory Body directly or indirectly concerns any Service User, the Provider must send a copy of it to the relevant Commissioner, in accordance with the timescales set out in Schedule 6C (Incidents Requiring Reporting Procedure) and in Schedule 6A (Reporting Requirements). 33.5 The Commissioners will have complete discretion (subject only to the Law) to use the information provided by the Provider under this SC33, Schedule 6C (Incidents Requiring Reporting Procedure) and Schedule 6A (Reporting Requirements) in any report which they make to any relevant Regulatory or Supervisory Body, any NHS Body, any office or agency of the Crown, or to any other appropriate regulatory or official body in connection with Serious Incidents, or in relation to the prevention of Serious Incidents, provided that in each case they notify the Provider of the information disclosed and the body to which they have disclosed it.    Incident Policy.pdf

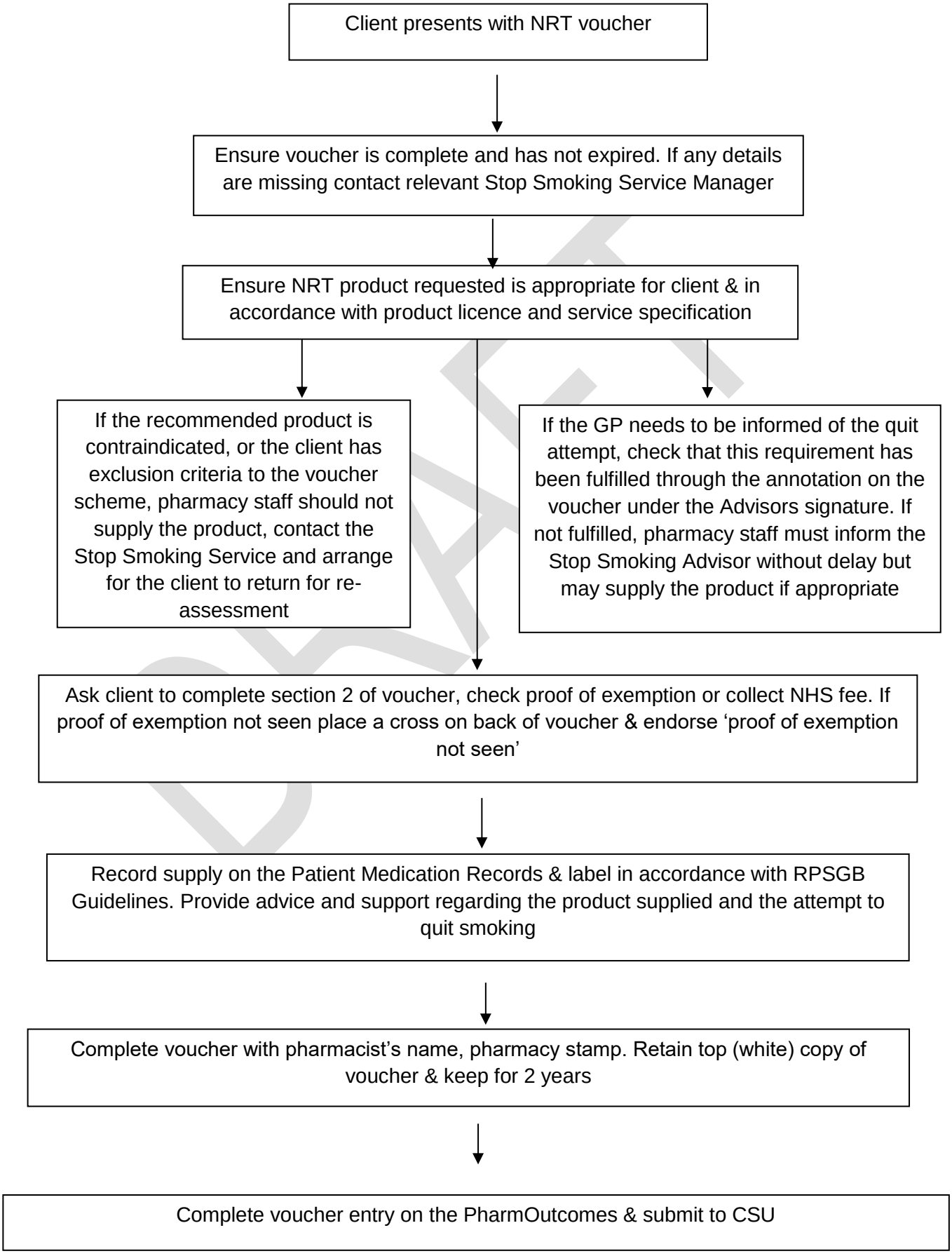
Appendix 1: LANCASHIRE NRT VOUCHER SCHEME FORMULARY

Product	Strength	Pack Size(s)	Maximum Daily Use	Side Effects
Nicotine Patch 16 hr	25mg 15mg 10mg	7/14 7 7	1 daily	Headache, Dizziness, Palpitations, Reversible Atrial Fibrillation, GI Discomfort, Hiccups, Nausea, Vomiting, Erythema, Urticaria, Itching.
Nicotine Patch 24 hr	21mg 14mg 7mg	7 7 7	1 daily	
Nicotine Gum (Adviser/Pharmacist to discuss flavour preferences with client)	2mg 4mg	96/105 96/105	15 a day	Headache, Dizziness, Palpitations, Reversible Atrial Fibrillation, GI Discomfort, Hiccups, Nausea, Vomiting, Erythema, Urticaria, Sore Mouth Or Throat, Jaw Muscle Ache, Allergic Reactions including Angioedema.
Nicotine Lozenge	2mg 4mg	72/96 72	15 a day	Anaphylactic Reactions, Irritability, Anxiety, Sleep Disorders, Nervousness, Depression, Dizziness, Headaches, Palpitations, Increased Heart Rate, Cough, Sore Throat, Nausea, Mouth Throat And Tongue Irritation, Vomiting, Diarrhoea, GI Discomfort, Flatulence, Hiccups, Heartburn, Dyspepsia, Rash, Fatigue, Malaise, Chest Pain
Nicotine Mini-Lozenge	1.5mg 4mg	20/60 20/60	15 a day	Anaphylactic Reactions, Irritability, Anxiety, Sleep Disorders, Nervousness, Depression, Dizziness, Headaches, Palpitations, Increased Heart Rate,

Cool Lozenge	2mg 4mg	20/80 20/80	15 a day	Cough, Sore Throat, Nausea, Mouth Throat And Tongue Irritation, Vomiting, Diarrhoea, GI Discomfort, Flatulence, Hiccups, Heartburn, Dyspepsia, Rash, Fatigue, Malaise, Chest Pain
Nicotine Inhalator	15mg	36 pack	6 a day	Headache, Dizziness, Palpitations, Reversible Atrial Fibrillation, GI Discomfort, Hiccups, Nausea, Vomiting, Erythema, Epistaxis, Running Nose, Sneezing, Watering Eyes, Coughing, Nasal Congestion
Nicotine Nasal Spray	500 micrograms	1 unit	64 sprays a day	Headache, Dizziness, Palpitations, Reversible Atrial Fibrillation, GI Discomfort, Hiccups, Nausea, Vomiting, Erythema, Epistaxis, Running Nose, Sneezing, Watering Eyes, Coughing, Nasal Congestion
Nicotine Mouth Spray	1 mg	1 unit	64 sprays per day up to 4 per hour	Dysgeusia, Headache, Hiccups, Nausea, Vomiting, Dyspepsia, Oral Soft Tissue Pain, Parasthesia, Stomatitis, Salivary Hypersecretion, Burning Lips, Dry Mouth, Dizziness, Palpitations, Coughing, Aphthous Stomatitis, Gingival Bleeding, Toothache, Pharyngeal Hypoaesthesia, Chest Pain, Dyspnoea, Reversible Atrial Fibrillation
Nicotine Strips	2.5mg	15/60	15 a day	Dizziness, sleep disorders, headache, cough, pharyngitis, nausea, pharyngolaryngeal pain, vomiting, dyspepsia, abdominal pain upper, diarrhoea, dry mouth, constipation, hiccups, stomatitis, flatulence, oral discomfort, hypersensitivity, angioedema, urticaria, ulcerative stomatitis, very rare anaphylaxis, nervousness, tremor, palpitations, tachycardia, dyspnoea, dysphagia, eructation, salivation, asthenia, fatigue, malaise, influenza type illness.

Appendix 2

STANDARD OPERATING PROCEDURE FLOWCHART: LANCASHIRE PHARMACY ENHANCED SERVICE NRT VOUCHER SCHEME



Appendix 3

Lancashire Voucher Scheme for the Supply of Nicotine Replacement Therapy (NRT)

AGREEMENT

Period of Agreement: 1st April 2021 to 31st March 2022

Period of Notice: 28 days by either party

I apply to be paid for the provision of Nicotine Replacement Therapy supplied at the premises named below, in line with the pharmacy enhanced service NRT voucher scheme service specification.

Name and designation of Pharmacy

Contractor (Block capitals): ……

Signature of Pharmacy

Contractor: **……**

Pharmacy Name: **……**

Pharmacy Address: **……**

……

……

Tel No: **……** Pharmacy Stamp

Date: **……**

Signature of representative

of Commissioning Support Unit : ***……***

Date: ***…… ……***

Relevant training courses attended/intend to attend within 6 months by supervising pharmacists and accredited pharmacy technicians who work routinely at the premises

Pharmacists Name* **(Please print and sign)**	**Date of course**	**Intended date of course**	**Organiser**	**Title**
And **Pharmacy Technician**** **(Please print and sign)**				

** By signing this form the pharmacist is declaring that they have completed the CPPE "Stop Smoking" open learning pack OR will complete the pack within 6 months from the date of this form.*

***Pharmacy Technicians must have attended the Stop Smoking Service training as a minimum requirement.*

Please return a copy to- Local Improved Services, NHS Midlands & Lancashire CSU, Jubilee House, Lancashire Business Park, Leyland, Lancashire, PR26 6TR.