

ITT SCHEDULE 1C

PRIMARY CARE PUBLIC HEALTH SERVICES

SERVICE SPECIFICATION

PROVISION OF COMMUNITY PHARMACY NICOTINE REPLACEMENT THERAPY VOUCHER SCHEME

1 INTRODUCTION

The Council is seeking a range of Community Pharmacies as providers of a local community based Sunderland Nicotine Replacement Therapy (NRT) Voucher Scheme. The scheme aims to ensure that people that smoke tobacco have access to appropriate Nicotine Replacement Therapy products that are listed for general sales to help them stop smoking.

This scheme does not include to the provision of varenicline (Champix). For details of provision of varenicline see Addendum One – Community Pharmacy Varenicline Scheme.

Providers will work in partnership with the Sunderland City Council, Council's representative organisation (currently the Live Life Well service) and other stakeholders to deliver a Programme that:

- Improves Service User access to Nicotine Replacement Therapy provision.
- Provides Nicotine Replacement Therapy dispensing in line with best practice and evidence as part of NHS Stop Smoking Service pharmacological products.
- Provides recommended pharmacological products to reduce withdrawal cravings from nicotine.
- Promotes prevention, early intervention and self-care.
- Contributes to local public health and tobacco control strategies, which have a commitment to reduce prevalence of smoking.

1.1 NATIONAL CONTEXT

The Council produces a Tobacco Joint Strategic Needs Assessment. Further information on national and local context can be found on <http://www.sunderland.gov.uk/index.aspx?articleid=11915>.

Tobacco control is a complex issue which requires commitment and contributions from a range of partners across Sunderland. Over the past 5 years, smoking prevalence has been falling nationally, regionally and locally, though smoking remains the greatest contributor to premature death and disease, killing 1 in every 2 long term smokers. It is estimated that up to half of the difference in life expectancy at birth between the most and least affluent groups is associated with smoking.

A wide range of diseases and conditions are caused by smoking, including cancers, respiratory diseases, coronary heart and other circulatory diseases, stomach and duodenal ulcers, erectile dysfunction, infertility, osteoporosis, cataracts, age related macular degeneration and periodontitis.

The national prevalence of smoking in adults aged 18 years and over has fallen over the past decade from 24% to 16.9% in 2015.

All of the commercially available forms of Nicotine Replacement Therapy (gum, transdermal patch, nasal spray, and sublingual tablets/ lozenges) are effective as part of a strategy to promote stop smoking. They increase the odds of quitting approximately 50% to 70% regardless of setting.

1.2 Local Context

Smoking remains the greatest contributor to premature death and disease across Sunderland. It is estimated that up to half the difference in life expectancy between the most and least affluent groups is associated with smoking.

The proportion of adults that smoke in Sunderland fell between 2010 and 2015 from 24.6% to 21.5%. In routine and manual groups smoking prevalence increased from 30.6% in 2011 to 34.1% in 2013 and has subsequently fallen to 29.4% in 2015. In Sunderland, 11.6% of 15 years olds and 18.7% of 16-17 year olds say that they smoke compared to 8.7% and 14.7% across England.

Rates of smoking are highest among young adults aged 18-24 years, males, people from socially and economically disadvantaged communities and people in routine and manual occupational groups. At ward level, the highest rates of smoking can be found in the Castle, Hendon and St. Anne's wards.

Smoking during pregnancy remains high. According to 2015/16 figures, 505 women in Sunderland were recorded as smoking at the time they gave birth; this equates to 18.0% of pregnant women compared to the England average of 10.6%. Smoking during pregnancy can cause serious pregnancy-related health problems. These include complications during labour and an increased risk of miscarriage, premature birth, still birth, low birth-weight and sudden unexpected death in infancy. Smoking during pregnancy also increases the risk of infant mortality by an estimated 40%.

One in twelve smokers in Sunderland access NHS Stop Smoking Services each year. In 2015/16, 47.7% of people setting a quit date had successfully quit at four weeks with 87% verified by use of a carbon monoxide (CO) monitoring, against a minimum standard of 85% of self-reported quits. NHS Stop Smoking Services have successfully targeted routine and manual occupational groups, among which the proportion of adults that smoke is highest. Young males and people from ethnic minorities are under-represented among Stop Smoking Service users.

2 PURPOSE AND OUTCOMES

2.1 Purpose

2.1.1 The Community Pharmacy Sunderland Nicotine Replacement Therapy Voucher Scheme aims to ensure that Service Users are able to access a range of pharmacological Nicotine Replacement Therapy products via local Community Pharmacies. As part of a broad programme of tobacco control, the Services aims to improve the health and wellbeing of smokers aged 12 years and over in Sunderland through a structured programme of support to prepare to stop smoking, successfully quit (at 4 weeks) and maintain the quit (to 12 weeks).

2.1.2 Supporting people to give up smoking will make a significant contribution to reducing health inequalities between Sunderland and England. Based on an assessment of smoking prevalence and outcomes, Sunderland has identified the following priority groups within the population for stop smoking support:

- a. People from routine & manual groups;
- b. Pregnant women;
- c. People from black and ethnic minority groups;
- d. People with serious mental health problems;
- e. People living in deprived areas.

2.1.3 Sunderland is signed up to the strategic aim to reduce tobacco related harm and to reduce adult smoking prevalence to 5% by 2025.

2.2 Vision

The Council's vision for the Community Pharmacy Sunderland Nicotine Replacement Therapy Voucher Scheme is of a accessible, evidence based programme focused on self-care and an integrated approach to lifestyle interventions that:

- Offers wide access to evidence based pharmacotherapies that are available from the General Sales List, where clinically appropriate, as aids to stop smoking and to help reduce nicotine cravings.
- Supports Service Users to self-care through the use of supporting information, website resources and approved applications (apps).
- Is delivered by suitably trained and competent Staff.
- Is delivered in a range of Community Pharmacies in all areas of Sunderland.

- Is person-centred, user-friendly and provides a positive Service User experience.

2.3 Programme Outcomes

- 2.3.1 The Provider will collectively contribute to the following indicators identified by the Public Health Outcomes Framework 2016-2019 from Public Health England <http://www.phoutcomes.info/>.

Domain	Indicator
Health Improvement	<p>Low birth weight of term babies</p> <p>Smoking prevalence at time of delivery</p> <p>Smoking prevalence in young people aged 15 years</p> <p>Smoking prevalence adults aged 18 years and over</p> <p>Smoking prevalence in routine and manual workers</p> <p>Smoking related deaths</p>

2.4 Individual Outcomes

The Provider will:

- 2.4.1 Offer a user friendly, non-judgemental, Service User centred service.
- 2.4.2 Provide easy access to the Community Pharmacy Sunderland Nicotine Replacement Therapy Voucher Scheme according to NICE guidelines <https://cks.nice.org.uk/smoking-cessation>.
- 2.4.3 Contribute towards the reduction of health harms associated with smoking.
- 2.4.4 Maximise the benefits of accessing community pharmacies, such as general health improvement and signposting to other services.

2.5 Branding, Marketing and Communications

- 2.5.1 Public Health England has produced a clear [brand identity for NHS Stop Smoking Services](#) (Smokefree) which distinguishes it from other commercially available offers. Sunderland NHS Stop Smoking Service will adopt this brand identity alongside locally produced resources bearing the 'Live Life Well' brand identity.

2.5.2 Providers can use the Smokefree brand, providing its use is in accordance with the branding guidelines. The Smokefree logo can be used with or without the NHS logo. Inclusion of the NHS logo is no longer permitted unless the Provider is part of the NHS family of organisations.

2.5.3 All promotional materials for the Service must bear the phrase “working with the NHS to provide stop smoking services”.

The Provider will:

2.5.4 Use the locally agreed supporting resources for the Programme as issued via the Council’s representative organisation (currently the Live Life Well Service).

2.5.5 Ensure that all communication about the Service uses the agreed brand identities and is compliant with Stop Smoking identity guidelines.

2.5.6 Use the dedicated Public Health England Campaign Resource Centre (<https://campaignresources.phe.gov.uk/resources/>) to obtain further marketing resources and national campaign materials.

2.5.7 Support local campaigns as identified by the Council’s representative organisation (currently the Live Life Well Service).

3 SERVICE CRITERIA

3.1 Inclusion Criteria

3.1.1 NHS Stop Smoking Service will be available to individuals who smoke tobacco, require help to quit (Clause 2.1.2) and are one or more of the following:

- a. Are aged 12 years and over;
- b. Live in Sunderland;
- c. Registered with a Sunderland GP;
- d. Work in Sunderland;
- e. Attend a school or college within Sunderland.

3.1.2 Nicotine Replacement Therapy products will be provided to Service Users (Clauses 2.1.2 and 3.1.1) presenting a valid Sunderland Nicotine Replacement Therapy Voucher for the scheme in Sunderland (Appendix 1) and must be:

- a. Registered with a Sunderland NHS Stop Smoking Service;
- b. Receiving advice and support from a trained Stop Smoking Adviser;
- c. Willing to take NRT as part of a structured quit attempt;
- d. Assessed as being suitable for NRT.

3.2 Exclusion Criteria

- 3.2.1 There are no exclusions to the Service on the basis of gender, race, sexual orientation, physical and/or mental impairment, pregnancy or any other protected characteristic, though the Provider will be able to exclude Service Users where:
- a. Acceptable behaviour is not upheld.
 - b. A professional risk assessment indicates that the Service User poses a serious risk to staff, other Service Users and/or members of the public.
- 3.2.2 Where a Service User is excluded from the Service, this must be discussed with the Service User and information must be provided about other available NHS Stop Smoking Services.

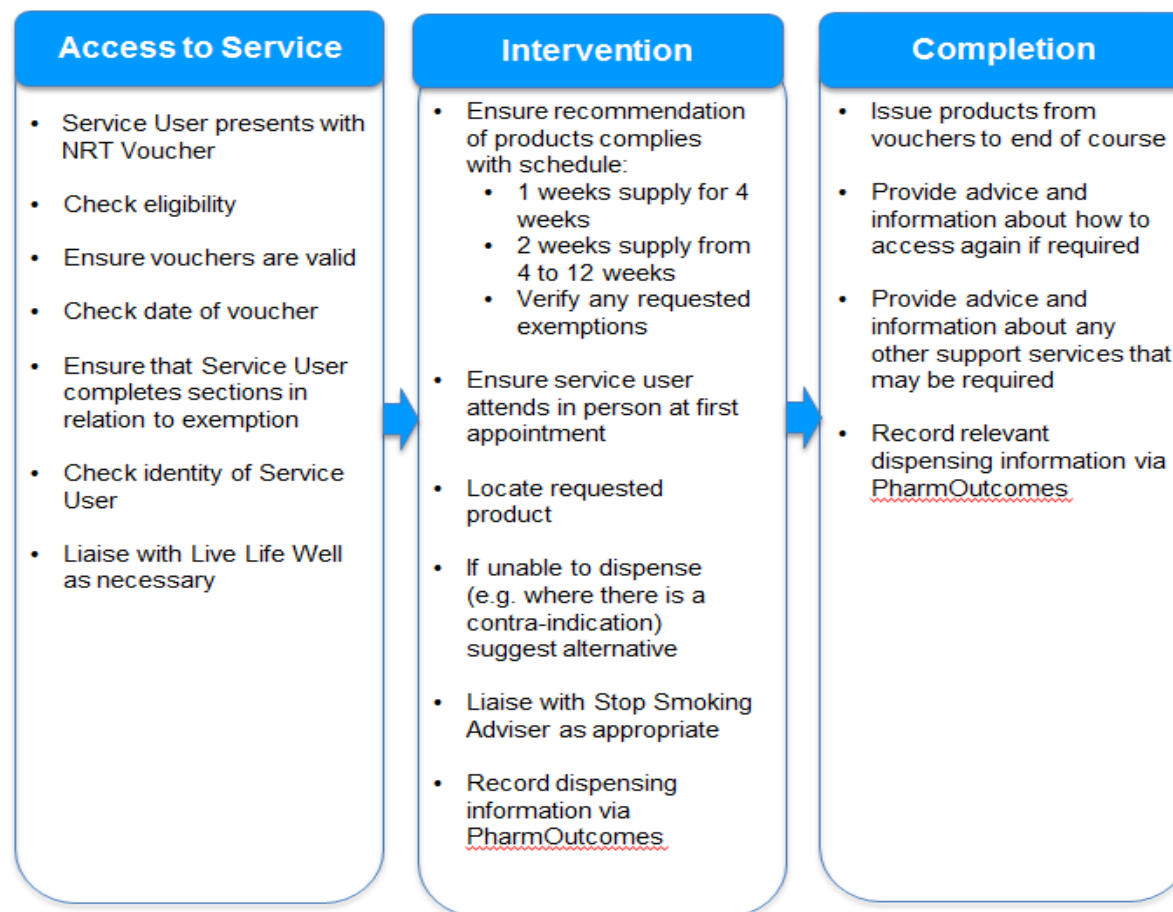
4 SERVICE DESCRIPTION

4.1 Service Overview

- 4.1.1 Community Pharmacy Sunderland Nicotine Replacement Therapy Vouchers are issued by the NHS Stop Smoking Service adviser who assesses the suitability of Service Users for the product(s).
- 4.1.2 Nicotine Replacement Therapy product(s) are issued after appropriate checks have taken place by a Community Pharmacist.
- 4.1.3 The Community Pharmacist will ensure that it is appropriate to dispense the recommended Nicotine Replacement Therapy product(s) to the Service User. In some circumstances the Community Pharmacist may suggest an alternative Nicotine Replacement Therapy product. Where an alternative Nicotine Replacement Therapy product(s) is recommended, the Community Pharmacist must have a discussion with the Service User and the NHS Stop Smoking Service adviser who made the initial recommendation.
- 4.1.4 All Nicotine Replacement Therapy products are classified as General Sales List products, and can be supplied directly from Community Pharmacies or other outlets without a prescription. The Sunderland Nicotine Replacement Therapy voucher scheme does NOT apply to varenicline (Champix) & bupropion (Zyban), as these are Prescription Only Medicines (POMs).
- 4.1.5 The Service will deliver a Community Pharmacy Sunderland Nicotine Replacement Therapy Voucher Scheme which enables access to Nicotine Replacement Therapy products for people who wish to stop smoking in Sunderland. This will include:
- a. Provision of pharmacological Nicotine Replacement Therapy products from the General Sales List;
 - b. Provision of advice and information for Service Users in relation to Nicotine Replacement Therapy products including potential side effects and contraindications.

- 4.1.6 The Provider will liaise with the recommending NHS Stop Smoking Service Adviser or the Council's representative organisation (currently the Live Life Well Service) to ensure:
- a. All recommendations for Nicotine Replacement Therapy products meet expected standards;
 - b. Any discrepancies in the recommendations are addressed;
 - c. All products are dispensed in line with local protocols.
- 4.1.7 The Provider will ensure that Service Users are informed of the times of the day they are able to access the Service.
- 4.1.8 The Service is divided into three areas of activity (Figure 1):
- a. Access to Service
 - b. Intervention
 - c. Completion
- 4.1.9 The care pathway for the Community Pharmacy Nicotine Replacement Therapy Scheme is summarised in the process flow chart (Figure 1 and Clauses 4.2 – 4.5).

Figure 1: Flow Chart Summary for the Community Pharmacy Nicotine Replacement Therapy Scheme



4.2 Access to Service

The Provider will:

- 4.2.1 Receive an approved Sunderland Voucher of Recommendation from Service Users. Service Users will have been issued with the Nicotine Replacement Therapy vouchers via one of the following routes:
 - a. Sunderland NHS Stop Smoking Service (GP, Community Pharmacy, Community);
 - b. Sunderland City Council, Council's representative organisation (currently the Live Life Well service).
- 4.2.2 Check that the Service User meets the eligibility criteria for the Service (Section 3.1).
- 4.2.3 Check that the Community Sunderland Pharmacy Nicotine Replacement Therapy Voucher presented is an approved Nicotine Replacement Therapy voucher (Appendix 1). If there is any uncertainty regarding the authenticity of the Nicotine Replacement Therapy voucher, the Provider is to contact the Council's representative organisation (currently the Live Life Well Service) for advice.
- 4.2.4 Ensure that the Sunderland Nicotine Replacement Therapy voucher has a unique provider code and serial number on.
- 4.2.5 On receipt of Community Pharmacy Nicotine Replacement Therapy Voucher, check the date of the Nicotine Replacement Therapy voucher to ensure that it has been presented within 28 calendar days of issue from the Stop Smoking Adviser. If the Nicotine Replacement Therapy voucher had been presented after 28 calendar days from issue, the Provider must contact the Stop Smoking Adviser to ensure that the Nicotine Replacement Therapy voucher is valid or contact the Council's representative organisation (currently the Live Life Well Service) for advice.
- 4.2.6 Ensure that the Service User completes all relevant sections of the Sunderland Nicotine Replacement Therapy Voucher in relation to exemptions from prescription fees to indicate whether they are required to pay a prescription fee. Where necessary, request relevant information from the Service User to establish that exemptions and records (where this has been received) are in place.

- 4.2.7 Ensure that the Service User has attended a Sunderland NHS Stop Smoking Service – as indicated by the completion of the “Recommended By” section on the Sunderland Nicotine Replacement Therapy voucher. Where there is any doubt about the Nicotine Replacement Therapy voucher authenticity, the Provider must contact the Council’s representative organisation (currently the Live Life Well Service) who will be able to make relevant checks. Nicotine Replacement Therapy products must not to be provided until checks have been satisfactorily completed.
- 4.2.8 Establish the identity of the Service User by requesting one form of identification selected from the following:
- a. Passport;
 - b. Driving Licence;
 - c. Utility Bill which is no more than 6 months old showing current address;
 - d. Bank Statement which is no more than 6 months old showing current address;
- 4.2.9 Ensure that where any doubts about the identity of a Service User arise, contact is made with the Council’s representative organisation (currently the Live Life Well Service) to seek further advice. Nicotine Replacement Therapy products must not to be provided until the Service User’s identity has been satisfactorily established.
- 4.2.10 Ask each Service User whether they are receiving pharmacotherapy aids to help them to stop smoking from another provider, and explain that Services may be withdrawn if it is found that the Service User is accessing multiple Providers for Stop Smoking Services and/or Stop Smoking aids at the same time.
- 4.2.11 Liaise with the Council’s representative organisation (currently the Live Life Well Service) to seek further advice where any unexpected surges in activity are experienced.

4.3 Intervention

The Provider will:

- 4.3.1 Ensure that the products recommended comply with the schedule for interventions (Appendix 2). During the first four weeks of the quit attempt the Service User will be provided with one week's supply of products at a time. After four weeks, two weeks supply will be provided up to a maximum of 12 weeks in total. The Service User may request two weeks supply during the first four weeks under exceptional circumstances, for example they are going on holiday or being admitted to hospital. In these instances the Provider must contact the NHS Stop Smoking Adviser directly to verify or the Council's representative organisation (currently the Live Life well Service) to seek further advice.
- 4.3.2 Ensure that the Service User is informed that they must attend in person for the first instance of supply of Nicotine Replacement Therapy products. The Service User must be informed that should a representative attend for the first supply of Nicotine Replacement Therapy products, products will not be supplied.
- 4.3.3 Review which products are recommended via the Sunderland Nicotine Replacement Therapy Voucher and ensure that the products are included within the approved list of products for the Service (Appendix 3).
- 4.3.4 Check which Nicotine Replacement Therapy combination is most effective to the needs of the Service User and where necessary make alterations to the Stop Smoking Adviser's recommendation.
- 4.3.5 Ensure that the products on the approved list are held in stock.
- 4.3.6 Provide advice and information in relation to the products provided to ensure that these products are suitable for the Service User (including though not limited to):
 - a. Potential side-effects;
 - b. Contraindications;
 - c. How to gain the best advantage from the use of the products.
- 4.3.7 Ensure that where high doses of Nicotine Replacement Therapy are recommended by the Stop Smoking Adviser, these are verified by the Provider as appropriate for the Service User and remain within British National Formulary guidelines.
- 4.3.8 In the event that the Provider is unable to supply the product in accordance with the recommendation on the Sunderland Nicotine Replacement Therapy Voucher, an alternative product must be offered.
- 4.3.9 Ensure that where the Provider is unable to supply products as per the Sunderland Nicotine Replacement Therapy Voucher of recommendation, this is discussed with the Service User and the Stop Smoking Service adviser who made the initial recommendation.

- 4.3.10 Ensure that where the Service User is eligible to pay prescription fees, this is indicated on the form and the amount to be paid is accurately recorded.
- 4.3.11 Ensure that details of NRT products dispensed are recorded on the Sunderland Nicotine Replacement Therapy Voucher prior to supplying to the Service User.
- 4.3.12 Supply the requested products in line with manufacturer's guidance.
- 4.3.13 Ensure that the "Supplied By" section of the Sunderland Nicotine Replacement Therapy Voucher is completed in full, as follows:
 - a. Name of supplier of product;
 - b. Signature of supplier of product;
 - c. Date product is supplied;
 - d. Contact number of supplier of product;
 - e. Community Pharmacy stamp to identify pharmacy.
- 4.3.14 Retain the Sunderland Nicotine Replacement Therapy Voucher as proof of dispensing requested products and to claim remuneration for at least 7 years.
- 4.3.15 Record the on-going supply of the products to each Service User via the commission IT System (currently "PharmOutcomes") and in line with Section 11.3 – Data Recording.
- 4.3.16 Complete the date of when the Sunderland Nicotine Replacement Therapy Voucher was submitted to the commission IT System (currently "PharmOutcomes") within the 'For Pharmacy Use Only' section.

The Provider must not:

- 4.3.17 Use the Sunderland Nicotine Replacement Therapy Voucher Scheme to make a recommendation for any product which are not part of the agreed list of pharmacological products (Appendix 3).

4.4 Completion

The Provider will:

- 4.4.1 Issue products as recommended by the Stop Smoking Service Adviser until the course of Sunderland Nicotine Replacement Therapy Vouchers is completed.
- 4.4.2 Ensure that where a Service User comes to the end of their course of Nicotine Replacement Therapy, they are advised how to access services in the event that they start smoking again.
- 4.4.3 Record the on-going supply of the products via the commission IT System (currently "PharmOutcomes") and ensure that data is accurately recorded (Clause 10.2)

4.5 Supply of Medication

The Provider will:

- 4.5.1 Ensure recommendations for pharmacotherapy are made from the agreed list of pharmacological products (Appendix 3).
- 4.5.2 Ensure that only original Sunderland Nicotine Replacement Therapy Vouchers are accepted. Photocopies must not be accepted. .
- 4.5.3 Ensure the approved Sunderland Nicotine Replacement Therapy Voucher (Appendix 1) is used by Stop Smoking Advisers when making recommendations and for the Provider to dispense nicotine replacement therapy as part of the Sunderland NHS Stop Smoking Service.
- 4.5.4 Ensure the Sunderland Nicotine Replacement Therapy Voucher (Appendix 1) is fully completed and states a recommended course of Nicotine Replacement Therapy which is compliant with the schedule of interventions (Appendix 2) and as follows:
 - a. During weeks 1-4 of the quit attempt, Nicotine Replacement Therapy voucher will enable one week's supply of NRT at a time;
 - b. During weeks 5-12 of the quit attempt Nicotine Replacement Therapy Vouchers will enable two week's supply of NRT at a time;
 - c. The provision of Nicotine Replacement Therapy vouchers will be for a maximum of 12 weeks.
 - d. The Service User may request two week's supply during weeks 1-4 of the quit attempt under exceptional circumstances (for example going on holiday or being admitted to hospital). The decision to grant such a request is at the professional discretion of the Stop Smoking Adviser, based on a balance of risk and benefits.
 - e. On all occasions, the decision to issue a Nicotine Replacement Therapy voucher for an Service User is the responsibility of the Stop Smoking Adviser providing the stop smoking support.
- 4.5.5 There is good evidence that combination NRT is more effective than single product NRT. In line with guidance Community Pharmacists are advised:
 - a. To prescribe patches (prolonged release) with an oral product (immediate release);
 - b. Not to provide two oral products (immediate release) simultaneously;
- 4.5.6 Upon a request for two oral products from a Service User, seek advice from the Council's representative organisation (currently the Live Life Well Service) before supplying the products.

5 MANAGEMENT OF PRODUCTS REQUESTED VIA STANDARD FP10 VOUCHER

5.1 Prescription Only Medications

5.1.1 Stop Smoking Advisers who are also GP prescribers or independent non-medical prescribers may prescribe prescription only approved stop smoking therapies (e.g. varenicline (Champix) & bupropion (Zyban) - these are not included within the formulary for this Service. In these instances, a Sunderland Nicotine Replacement Therapy voucher of recommendation will not be provided as this activity is not part of the Community Pharmacy Sunderland Nicotine Replacement therapy voucher scheme and will not be remunerated. Dispensing costs must be recovered via the Community Pharmacy's standard processes in relation to prescriptions.

5.2 Nicotine Replacement Therapy Provided via Standard FP10 Prescriptions

5.2.1 Stop Smoking Advisers who are also a GP Prescriber or Independent Non-Medical Prescriber must prescribe prescription only pharmacological therapy (bupropion or varenicline) as an aid to stop smoking on an FP10 prescription. All other NRT products must be recommended using the using the Sunderland Nicotine Replacement Therapy Voucher Scheme.

5.2.2 If Stop Smoking Advisers who are also GP prescribers or independent non-medical prescribers prescribe Nicotine Replacement Therapy products that are listed for general sales using an FP10 prescription, rather than a Sunderland Nicotine Replacement Therapy voucher of recommendation, this activity is not part of the Community Pharmacy Sunderland Nicotine Replacement Therapy Voucher Scheme and will not be remunerated via the scheme.

Dispensing costs must be recovered via the Community Pharmacy's standard processes in relation to prescriptions.

6 INTERDEPENDENCIES WITH OTHER SERVICES

6.1 In order to deliver a holistic Service the Provider must have strong working relationships with a range of partners including but not limited to:

- a. Sunderland Integrated Wellness Model (currently Live Life Well);
- b. General Medical Practices;
- c. Community Pharmacies;
- d. Sunderland City Council.

6.2 It will be the responsibility of the Community Pharmacy to facilitate onward referrals (where applicable) into other services such as the Sunderland City Council, Council's representative organisation (currently the Live Life Well Service), General Practice or other Community Pharmacies.

- 6.3 Staff delivering the Sunderland Nicotine Replacement Therapy Voucher Scheme must promote improving health wherever possible and it will be the responsibility of the Community Pharmacy to facilitate onward referrals into other general health care services.

7 GOVERNANCE ARRANGEMENTS

7.1 Legislation and Guidance

7.1.1 In line with the Department of Health and National Institute of Clinical Excellence guidelines, the Provider must operate in compliance with the following core guidance documents (including though not limited to):

- a. A Smokefree Future – a Comprehensive Tobacco Control Strategy for England (DH, February 2011)
- b. Healthy lives, healthy people: a tobacco control plan for England (Department of Health, 2011)
- c. Stop Smoking Service Delivery and Monitoring Guidance 2011/12 (DH, March 2011)
- d. Excellence in Tobacco Control: 10 High Impact Changes (May 2008)
- e. NICE public health intervention guidance 10: Smoking cessation services in primary care, pharmacies, local authorities and workplaces, particularly for manual working groups, pregnant women and hard to reach communities (2008)
- f. NICE public health intervention guidance 1: Brief Interventions and referral for smoking cessation in primary care and other settings (March 2006)
- g. PH5 Workplace interventions to promote smoking cessation (NICE, 2007)
- h. NICE public health guidance 6: Behaviour change (Oct 2007) (covers individual level, community level and population level programmes, planning, delivery and evaluation)
- i. TA123 Smoking cessation – varenicline (NICE, 2007)
- j. NICE public health guidance 26: Quitting smoking in pregnancy and following childbirth (2010)
- k. NICE public health guidance 39: Smokeless tobacco cessation - South Asian communities (2012)
- l. NICE public health guidance 45: Tobacco harm reduction (2013)
- m. QS43 Smoking cessation: supporting people to stop smoking (NICE, 2013)

7.1.2 The Provider must adopt and operate in compliance with new guidance documents as these are published.

- 7.1.3 In accordance with the Health and Social Care Act 2008, where regulated activities are provided, the Provider must register these with the Care Quality Commission (Refer to <http://www.cqc.org.uk/organisations-we-regulate/registering-first-time/regulated-activities>).

7.2 Clinical Governance

- 7.2.1 The Provider will manage clinical governance for the Service in line with requirements stated in the General Specification (Clause 11.2).

7.3 Information Governance

- 7.3.1 The Provider will manage information governance for the Service in line with requirements stated in the General Specification (Clause 11.3).

8 EQUIPMENT AND FACILITIES

8.1 Stock Control

The Provider will:

- 8.1.1 Ensure that adequate stock levels are maintained at all times to enable products to be supplied in line with the approved list of products for the service (see Appendix 3).

8.2 Consultation Area

- 8.2.1 The Provider will ensure that a private consultation area is available for the delivery of the Service which:
- a. Enables the Service User and the Community Pharmacist to meet and ensure a confidential conversation can be undertaken, without being overheard by other visitors to the pharmacy, or by staff undertaking their normal duties;
 - b. Is clearly designated as a private consultation area and is distinct from the general public areas of the pharmacy.

8.3 Programme Governance

- 8.1 Local level governance for the programme is currently managed by the Council's representative organisation (currently the Live Life Well Service) and delivered by Live Life Well Mentors.
- 8.2 The role of the mentor is to quality assure the service and provide guidance to providers on the operational delivery including but not limited to:
- a. Use of Sunderland Nicotine Replacement Therapy Vouchers;
 - b. Compliance in core training;

- c. Providing local Stop Smoking resources;
- d. Providing local marketing/ campaign materials.

9. QUALITY AND SAFETY

9.1 Workforce

- 9.1.1 Each Provider will be accountable for ensuring that skills and knowledge of Staff are up to date.
- 9.1.2 Knowledge and skills required for the Service will be verified using the Declaration of Competence (DoC) system to assure the Council that the Provider's Staff are competent to deliver the Service (Appendix 4 and Appendix 5).
- 9.1.3 The Provider must demonstrate that they have completed the Centre for Pharmacy Postgraduate Excellence (CPPE) distance learning course "Smoking - theLearningpharmacy.com" (Refer to www.cppe.ac.uk).
- 9.1.4 Competencies must be reviewed and confirmed at least once every three years as evidence of continuing professional development and maintenance of competence as stated within the DoCs.
- 9.1.5 The Provider has a duty to ensure that all Staff delivering the Service has the relevant knowledge and are appropriately trained in the operation of the Service.
- 9.1.6 The Provider must ensure that Staff are trained in dealing with Service Users in a person-centred, user-friendly, confidential and non-judgmental manner.
- 9.1.7 The Provider must ensure that all Staff delivering the Service are aware that they have a professional responsibility to develop, reinforce and update their knowledge and skills. The Provider must ensure that systems are in place to monitor Staff development. Further information can be found at: http://www.ncsct.co.uk/usr/pub/NCSCCT_training_standard.pdf
- 9.1.8 The Provider may authorise Staff, who are suitably trained, to undertake and record data. The overall consultation and clinical responsibility for the supply of Nicotine Replacement Therapy products or onward referral, lies with the Provider.
- 9.1.9 The Provider must ensure that safeguarding adults and children is considered and managed at all times in line with the requirements stated in the General Specification (Clause 11.5).
- 9.1.10 The Provider must ensure that Staff are trained in dealing with Service Users in a person-centred, user-friendly, confidential and non-judgmental manner.

9.1.11 The Provider will work towards the principles of the You're Welcome Quality Criteria. Refer to www.youngpeopleshealth.org.uk/yourewelcome/

10. QUALITY REQUIREMENTS

10.1 The Provider will ensure that the Service is delivered in line with the following quality requirements:

No	Quality Measures	Frequency	Methodology
1	Demonstrate that all Staff involved in the provision of the Service have successfully completed the CPPE Declaration of Competency	At commencement of Service and in line with Declaration of Competency Requirements	Declaration of Competency checklists completed by Provider and supplied to the Council.
2	The Provider will review the standard operating procedures for the Service on an annual basis.	Annual	Standard operating procedure available for inspection by the Council describing review activities, findings and areas for improvement.
3	Participate in audits of service provision.	Annual	The Council will audit the Service to ensure that delivery is in line with the service specification. The Provider will ensure that access to premises and any relevant information is made possible to Council staff.
4	Co-operate with any locally agreed assessment of Service User experience.	As required by the Council	The Council will inform the Provider in the event of any Service User experience exercises and ensure that access to premises and any relevant information is made possible to Council staff or their appointed representatives.

No	Quality Measures	Frequency	Methodology
5	Ensure there is an appropriate consultation area available for the delivery of the Service to ensure that the needs of Service Users can be assessed and met in a confidential manner.	Local reports/ review meetings	The provider will ensure that access to premises and any relevant information is made available to Council staff for the purposes of verification.
6	The Provider will ensure that all Staff will complete all necessary documentation and record data as agreed with the Council, to enable monitoring and evaluation of the Service.	Activity information submitted monthly.	Activity information will be available to the commission IT System (currently "PharmOutcomes"). Other information will be available on request.
7	The Provider must maintain appropriate records to ensure effective on-going service delivery and audit. Records will be confidential and must be stored securely and for the length of time expressed in local NHS record retention policies.	On-going	The Council will audit the Service to ensure that delivery is in line with the service specification. The Provider will ensure that access to premises and any relevant information is made available to Council staff.
8	The Provider will need to share relevant information with other health care professionals and agencies, in line with locally determined confidentiality arrangements, including, where	On-going	The Council will audit the Service to ensure that delivery is in line with the service specification. The Provider will ensure that access to premises and any relevant information is made possible to Council staff.

No	Quality Measures	Frequency	Methodology
	appropriate, the need for the consent of the Service User to share the information.		

10.2 Data Reporting

The Provider will:

10.2.1 Record service delivery information within the Council's Contracted Provider's IT System (currently "PharmOutcomes") to enable monitoring of activity.

10.2.2 Register all Service Users on the Council's Contracted Provider's IT System (currently "PharmOutcomes") including the following data items:

- a. Registration Date
- b. Name
- c. Date of Birth
- d. Gender
- e. Ethnicity
- f. Postcode
- g. Address
- h. Levy Status
- i. GP Surgery

10.2.3 Record all transactions on the Council's Contracted Provider's IT System (currently "PharmOutcomes") including the following data items:

- a. Nicotine Replacement Therapy Voucher Number
- b. Provider ID code (GP Practice Code or Pharmacy Code or Community Provide Code)
- c. Nicotine Replacement Therapy Voucher Issue Date
- d. Nicotine Replacement Therapy Voucher Provider
- e. Client Name
- f. Date supplied
- g. Supply Information – Patch 16 hour
 - i. Type
 - ii. Quantity
- h. Supply Information – Patch 24 hour
 - i. Type
 - ii. Quantity
- i. Supply Information – Microtab
 - i. Type
 - ii. Quantity
- j. Supply Information – Lozenge
 - i. Type
 - ii. Quantity

- k. Supply Information – Mini Lozenge
 - i. Type
 - ii. Quantity
- l. Supply Information – Gum
 - i. Type
 - ii. Quantity
- m. Supply Information – Nasal Spray
 - i. Type
 - ii. Quantity
- n. Proof of ID seen
- o. Serial number of Nicotine Replacement Therapy Voucher
- p. Levy Status
- q. Notes

10.2.4 The Provider will manage data reporting for the Service in line with the requirements stated in the General Specification (Clause 11.3).

11 PRICING AND PAYMENT

11.1 Price Schedule

11.1.1 A fee of £3.50 will be paid for the initial assessment and first 1 week's supply of a valid Sunderland Nicotine Replacement Therapy Voucher. Evidence for this is in the form of Nicotine Replacement Therapy Voucher number 1.

11.1.2 A fee of £1.30 will be paid for each instance of dispensing for the life of the programme of Sunderland Nicotine Replacement Therapy Vouchers issued to the Service User.

11.1.3 Fixed costs of Nicotine Replacement Therapy products plus VAT will be reimbursed. Only products approved for use under the Community Pharmacy Nicotine Replacement Therapy Scheme will be reimbursed (Appendix 3).

11.2 Payment Terms

11.2.1 Payment for the Service will be made monthly in arrears.

11.2.2 The Provider must upload all data within 7 days of the end of each month to ensure it is available to the Council for download.

11.2.3 The Council will access its Contracted Provider's IT System (currently "PharmOutcomes") following the Provider uploading data (Clause 11.2.2) to access automatically generated invoices and supporting data (Terms and Conditions 15.4).

11.2.4 Payment to the Provider will be made no later than 30 days following the date of receipt of the invoice by the Council (Terms and Conditions 15.4).

- 11.2.5 Where data is not submitted within the required timescales (clause 11.2.2) activity data will be retained and payment will be made in the following month.
- 11.2.6 Where Sunderland Nicotine Replacement Therapy Vouchers are presented later than 28 days after their date of recommendation from the Stop Smoking Adviser, the Councils Contracted Provider's IT System (currently "PharmOutcomes") will not allow payment to be made for that voucher.

APPENDIX 1

APPROVED SUNDERLAND NICOTINE REPLACEMENT THERAPY VOUCHER



SUNDERLAND NRT VOUCHER OF RECOMMENDATION

Please complete in BLOCK CAPITALS.

LLW Voucher No. _____ / of 8

Date of issue: _____ / _____ / _____

Provider Details: Voucher is only valid for 28 calendar days from the date of issue

Advisor Name: _____
 Contact Number: _____
 Organisation name and address: _____
 Postcode: _____

Client Details

Forename(s): _____ Surname: _____
 Date of Birth: _____ Age: _____
 Address: _____
 Postcode: _____
 G.P. Practice: _____ Address: _____

Is the patient pregnant? **Yes / No / N/A**

If pregnant: The risks and benefits of using NRT during pregnancy have been discussed with this client **Yes / No**

Product(s): Weeks 1 – 4 (1 weeks supply ONLY) Weeks 5 – 12 (2 weeks supply ONLY)

Product	Strength	Pack Size	Number of Packs
NRT Patch 16 hours			
NRT Patch 24 hours			
NRT Microtab			
NRT Lozenges			
NRT Mini Lozenges			
NRT Gum			
NRT Nasal Spray			
Other			

Client Receipt of Voucher

Proof of I.D. **Yes / No / N/A** Client Signature: _____
 Client Name (BLOCK CAPITALS): _____

Serial No. _____

This is property of Sunderland City Council. This voucher is not valid in Stop Smoking Services located outside the boundaries of Sunderland. In the event that it is presented in another area, please contact - Sunderland Live Life Well Service on 0191 565 3482



PHARMACY USE ONLY

Supplied by:	
Signature: _____	Pharmacy stamp
Name: _____	
Date of issue: _____	
Tel.: _____	

Don't pay – Indicate exemption category (put X mark)

- | | | |
|---|--------------------------|---|
| A | <input type="checkbox"/> | is under 16 years of age |
| B | <input type="checkbox"/> | is 16, 17 or 18 and in full-time education |
| C | <input type="checkbox"/> | is 60 years of age or over |
| D | <input type="checkbox"/> | has a maternity exemption certificate |
| E | <input type="checkbox"/> | has a medical exemption certificate |
| F | <input type="checkbox"/> | has a prescription pre-payment certificate |
| G | <input type="checkbox"/> | has a valid War Pension exemption certificate |
| L | <input type="checkbox"/> | is named on a current HC2 charge certificate |
| H | <input type="checkbox"/> | gets Income Support |
| K | <input type="checkbox"/> | gets Income Based Jobseeker's Allowance (JSA(IB)) |
| M | <input type="checkbox"/> | is entitled to, or named on, a valid NHS Tax Credit Exemption Certificate |
| S | <input type="checkbox"/> | has a partner who gets Pension Credit guarantee credit (PCGC) |

Payment: I have paid £

I am the: Patient Patient's representative

Signed: _____ Date: _____

Address if different from above: _____

For Pharmacy use only	
Cross if evidence of exemption not seen? <input type="checkbox"/>	
Date submitted to PharmOutcomes for payment	/ /

For LLW use only

APPENDIX 2

SCHEDULE OF INTERVENTIONS

ONE TO ONE

Week No	Amount of Time of at Least	Nicotine Replacement Therapy Voucher Supply	Number of NRT Days
Initial assessment	30 minutes	0	0
Second appointment to set a quit date	20 minutes	0	0
Week 0	15 minutes	1 weeks supply	1 to 7
Week 1	15 minutes	1 weeks supply	8 to 14
Week 2	15 minutes	1 weeks supply	15 to 21
Week 3	15 minutes	1 weeks supply	22 to 28
Week 4	15 minutes	2 weeks supply if on 12 week programme.	29 to 42
After 4 Weeks the Service User should be seen Every 2 Weeks			
Week 6	15 minutes	2 weeks supply	43 to 56
Week 8	15 minutes	2 weeks supply	57 to 70
Week 10	15 minutes	2 weeks supply	71 to 84
Week 12	15 minutes	No Nicotine Replacement Therapy Voucher but Carbon Monoxide (CO) reading and sign off	Finish NRT

GROUPS

Week No	Amount of Time of at Least	Nicotine Replacement Therapy Voucher Supply	Number of NRT Days
Initial assessment	30 minutes	0	0
Second appointment to set a quit date	20 minutes	0	0
Week 0	15 minutes	1 weeks supply	1 to 7
Week 1	60 minutes	1 weeks supply	8 to 14
Week 2	60 minutes	1 weeks supply	15 to 21
Week 3	60 minutes	1 weeks supply	22 to 28
Week 4	60 minutes	2 weeks supply if on 12 week programme.	29 to 42
After 4 Weeks the Service User should be seen 2 Weekly			

Week 6	15 minutes	2 weeks supply	43 to 56
Week 8	15 minutes	2 weeks supply	57 to 70
Week 10	15 minutes	2 weeks supply	71 to 84
Week 12	15 minutes	No Nicotine Replacement Therapy Voucher but Carbon Monoxide (CO) reading and sign off	Finish NRT

APPENDIX 3

AGREED LIST OF PHARMACOTHERAPIES FOR USE WITHIN THE SUNDERLAND NHS STOP SMOKING SERVICE

All Nicotine Replacement Therapy product prices are set as of May 2017 in accordance to NHS Dictionary of Medicines and Devices. Prices are updated on a weekly basis and will automatically reflect the Council's commission IT System (currently "PharmOutcomes").

Preparation	Strength	Maximum Daily Dose	Instructions	Comments	Price
Patches	10mg/16 hours 15mg/16 hours 25mg/16 hours	1 patch a day regardless of strength	<ul style="list-style-type: none"> Apply on waking to dry, non-hairy skin on hip, chest or upper arm, and remove 16 hours later, usually before bedtime. Rotate sites 	<ul style="list-style-type: none"> Suitable for smokers with regular smoking pattern and low level of behavioural dependence. Patches give a constant release of nicotine. Not suitable for occasional smokers 	Brand: Nicorette Invisi <ul style="list-style-type: none"> Prices are for 7 patches 10mg/16 hours - £10.99 15mg/16 hours - £11.10 25mg/16 hours - £11.15
Patches	7mg/24 hours 14mg/24 hours 21mg/24 hours	1 patch a day regardless of strength	<ul style="list-style-type: none"> Apply in the morning to dry, non-hairy skin on hip, chest or upper arm, and remove and replace 24 hours later. Rotate sites 	<ul style="list-style-type: none"> Recommended for those who smoke within 30 minutes of waking or smoke at night. Patches give a constant release of nicotine. Not suitable for occasional smokers 	Brand: NiQuitin <ul style="list-style-type: none"> £9.97 for 7 patches

Preparation	Strength	Maximum Daily Dose	Instructions	Comments	Price
Sublingual tablets (microtabs)	2mg tablets	40 tablets in 24 hours	<ul style="list-style-type: none"> • Tablet should be placed under the tongue and allowed to slowly dissolve. • It should be moved around under the tongue to prevent irritation. • For patients smoking ≤ 20 cigarettes daily, 2mg every hour. Can be increased to 4mg every hour in patients who fail to stop smoking or have significant withdrawal symptoms. • For patients smoking ≥ 20 cigarettes daily, 4mg every hour. 	<ul style="list-style-type: none"> • Continue treatment for up to 3 months before reducing the dose • It is discreet and flexible and provides good dose control 	Brand: Nicorette Microtabs <ul style="list-style-type: none"> • £13.12 for 100 tablets
Lozenges	1.5mg, 2mg, 4mg	15 lozenges daily	<ul style="list-style-type: none"> • Put lozenge in mouth and allow to slowly dissolve; • periodically move it from one side of the mouth to the other. • Lozenge should not be chewed or swallowed whole 	<ul style="list-style-type: none"> • Lozenges last 10-30 minutes depending on size. • Continue treatment for 6-12 weeks before attempting dose reduction • Users should not eat or drink while the lozenge is in the mouth 	Brand: NiQuitin <ul style="list-style-type: none"> • £9.97 for 72 1.5mg, 2mg 4mg
Mini-Lozenges	4mg and 1.5mg	15 lozenges daily	<ul style="list-style-type: none"> • Put lozenge in mouth and allow to slowly dissolve; 	<ul style="list-style-type: none"> • Lozenges last 10-30 minutes depending on size. 	Brand: NiQuitin Minis <ul style="list-style-type: none"> • £3.50 for 20 4mg and 1.5mg

Preparation	Strength	Maximum Daily Dose	Instructions	Comments	Price
			<ul style="list-style-type: none"> periodically move it from one side of the mouth to the other. Lozenge should not be chewed or swallowed whole 	<ul style="list-style-type: none"> Continue treatment for 6-12 weeks before attempting dose reduction Suitable for smokers who smoker 20 cigarettes or less per day Users should not eat or drink while the lozenge is in the mouth 	<ul style="list-style-type: none"> £9.57 for 60 4mg and 1.5mg
Nicotine medicated gum	2mg 4mg	15 pieces of either strength	<ul style="list-style-type: none"> Chew one piece when the urge to smoke occurs. Chew until a peppery/ tingling feeling occurs, flatten and park between the gum and the cheek. Chew and park several times per piece. Nicotine is released over 30 minutes of slow intermittent chewing - to release taste. 	<ul style="list-style-type: none"> Allows good control of nicotine dose. Not permitted on mental health wards. 	Brand: Nicotinell <ul style="list-style-type: none"> £8.26 for 96 2mg pieces £10.26 for 96 4mg pieces
Nicotine nasal spray	0.5mg/ spray	64 sprays daily	<ul style="list-style-type: none"> Tilt head and use one squirt in each nostril when the urge to smoke occurs, up to twice an hour for 16hours/ day. When withdrawing from therapy, the dose can be 	<ul style="list-style-type: none"> Rapid nicotine delivery - better for very dependent smokers. Recommended for those who smoke ≥ 20 cigarettes a day 	Brand: Nicorette <ul style="list-style-type: none"> £14.84 for 1x10ml spray

Preparation	Strength	Maximum Daily Dose	Instructions	Comments	Price
			gradually reduced to 1 spray in 1 nostril.		

APPENDIX 4

DECLARATION OF COMPETENCE

Sunderland Nicotine Replacement Therapy (NRT) Voucher Scheme in Community Pharmacy

The Declaration of Competence (DoC) system has been given national support after a series of pilots in England. The purpose of the DoC is to review pharmacists' and pharmacy technicians' competence to deliver a locally commissioned service and to assure commissioners they have the appropriate knowledge, skills and behaviours to deliver a high-quality, consistent service. The new criteria detailed below now replace any previous accreditation system.

The DoC has been endorsed by NHS England, Health Education England and Public Health England.

The DoC guidance for the **Sunderland Nicotine Replacement Therapy (NRT) Voucher Scheme in Community Pharmacy** service is available to download from the CPPE website using the link below:

<https://www.cppe.ac.uk/services/declaration-of-competence>

Each Public health Service has a framework that sets out the core professional competences for that service. The framework allows self-assessment of competence and outlines the recommended learning to enable self-declaration.

The **training requirements** to meet the competencies in the DoC and enable self-certification, to deliver the Sunderland Nicotine Replacement Therapy (NRT) Voucher Scheme in Community Pharmacy Public Health commissioned service in Sunderland are set out below in box 1:

Box 1: Learning and Assessments

Safeguarding Children and Vulnerable Adults Knowledge (1 hour)

- Complete the CPPE Safeguarding children and vulnerable adults e-learning.
- Pass the safeguarding e-assessment.

Consultation Skills for Pharmacy Practice (3 hours)

- Complete the CPPE Consultation Skills e-learning or distance learning.
- Pass the consultation skills e-assessment.

Smoking eLearning - each challenges take 10 to 15 minutes and covers:

- New methods of engaging with patients and the public
- Ways to develop and run an effective health promotion campaign in your pharmacy
- Providing advice and signposting on self-care and public health
- Ways to develop and deliver a successful pharmacy service
- Supporting individuals presenting with a new prescription
- Advising appropriately a patient requesting an OTC medicine
- Identifying and meeting the professional development needs of the pharmacy team
- Becoming more confident in dealing with therapeutic challenges and prescription interventions.

Additional Local Requirements

Basic Awareness (Alerter) Training in Safeguarding Adults (level 1)

- Complete the [Sunderland Safeguarding Adults Board e-learning](#) (45 minutes).

Basic Awareness (Foundation) Training in Safeguarding Children

- Complete the Sunderland Safeguarding Childrens Board approved Training www.sunderlandscb.com in Safeguarding Childrens (1 to 2 hours)

Pre-reading

- Read and understand the Gillick Competence and are able to assess young people under the age of 16 years for Gillick Competence. Refer to www.cgc.org.uk/content/nigels-surgery-8-gillick-competency-and-fraser-guidelines

Standard Operating Procedures for Self-Certification

The Provider will:

1. Access the declaration of competence guidance from the CPPE website using the link below:

<https://www.cppe.ac.uk/services/declaration-of-competence>
2. Download and complete the declaration of competence (DoC) self-assessment tool for Sunderland Nicotine Replacement Therapy (NRT) Voucher Scheme in Community Pharmacy.
3. Review the DoC self-assessment tool to identify any learning needs and refer to the training requirements for guidance.
4. Complete any necessary training, ensuring completion of the mandatory CPPE Safeguarding children and vulnerable adults e-learning.
5. Print and sign the declaration of competence and qualifications certificate.
6. Send a copy of the signed DoC documentation
 - Declaration of Competence and qualification certificate
 - Completed Pharmacist Authorisation checklist

Send a copy of the following documentation to Public Health Commissioning Room 3.103, Civic Centre, Sunderland, SR2 7DN or email to: PHenquiries@sunderland.gov.uk

The Council will issue a letter of authorisation to enable provision of the Service on receipt and approval of all of the above documentation.

Under the CPPE e-assessments the DoC is valid for three years. If however there have been significant changes to delivery of the Service, the Provider will be expected to revisit the DoC and resubmit this to the Council. As a guide, the CPPE e-assessments should be passed every three years. The Provider may choose to attend a course to revise knowledge, skills and behaviours to ensure the DoC criteria are met.

Signed Date

Print name

Name and Address of Organisation.....

.....

Email address.....