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## DIRECTIONS

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# THE NATIONAL HEALTH SERVICE ACT 2006

## The Pharmaceutical Services (Smoking Cessation Service) (England) Directions 2022

The Secretary of State gives the following Directions in exercise of the powers conferred by sections 127, 128, 272(7) and (8)(a) and 273(1) of the National Health Service Act 2006(a).

### Citation, commencement, extent, application and interpretation

1.—(1) These Directions may be cited as the Pharmaceutical Services (Smoking Cessation Service) (England) Directions 2022.

(2) These Directions, apart from direction 4, come into force on 10th March 2022.

(3) Direction 4 comes into force on 1st April 2022.

(4) These Directions extend to England and Wales but apply only to England.

(5) In these Directions, “the 2013 Directions” means the Pharmaceutical Services (Advanced and Enhanced Services) Directions 2013(b).

### Amendment of direction 2 of the 2013 Directions

2.—(1) Direction 2 of the 2013 Directions (interpretation) is amended as follows.

(2) At the appropriate places in the alphabetical order insert—

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(a) 2006 c. 41. Section 127 has been amended by the Health and Social Care Act 2012 (c. 7) (“the 2012 Act”), Schedule 4, paragraph 64. Section 128 has been amended by the 2012 Act, Schedule 4, paragraph 65.

(b) Signed on 12th March 2013, and amended by: the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2013, signed on 16th September 2013; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2013, signed on 6th December 2013, which also revoked the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2013; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2014, signed on 12th March 2014; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2014, signed on 5th December 2014; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2015, signed on 15th September 2015; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2016, signed on 30th August 2016; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No.2) Directions 2016, signed on 30th November 2016; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2017, signed on 29th August 2017; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2018, signed on 8th March 2018; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2018, signed on 31st August 2018; and the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2019, signed on 13th March 2019; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2019, signed on 22nd August 2019; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 3) Directions 2019, signed on 11th September 2019, the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 4) Directions 2019, signed on 24th October 2019; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2020, signed on 6th March 2020; the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) Directions 2020, signed on 27th March 2020; and the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Amendment) (England) Directions 2020, signed on 30th June 2020; the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) (No.2) Directions 2020, signed on 28th August 2020; the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) Directions 2021, signed on 29th March 2021; the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Amendment) (England) Directions 2021, signed on 29th June 2021; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2021, signed on 1st September 2021; and the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Further Amendments) (England) Directions 2021, signed on 30th September 2021.

““SCS” means the Smoking Cessation Service, which is the advanced service described in direction 7BH(2);” and

““SCS service specification” means the service specification for the SCS, produced by the NHSCB, dated 9th March 2022(a);”.

### **Renumbering of second direction 7BF and direction 7BG**

3. As regards the directions inserted into the 2013 Directions by direction 7 of the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Further Amendments) (England) Directions 2021(b)—

- (a) direction 7BF (Community Pharmacy Hypertension Case-Finding Advanced Service: general matters and preconditions to making arrangements) is renumbered direction 7BG; and
- (b) direction 7BG (Community Pharmacy Hypertension Case-Finding Advanced Service: ongoing conditions of arrangements) is renumbered direction 7BH.

### **Revocation of directions 7BE and 7BF of the 2013 Directions and consequential amendments**

4.—(1) Directions 7BE of the 2013 Directions(c) (Community Pharmacy COVID-19 Lateral Flow Device Distribution Service: general matters and preconditions to making arrangements) and 7BF of the 2013 Directions(d) (Community Pharmacy COVID-19 Lateral Flow Device Distribution Service: ongoing conditions of arrangements) are revoked.

(2) In direction 2 of the 2013 Directions(e) (interpretation), omit the definitions of “CFCLFDDS”, “CFCLFDDS service specification” and “LFD”.

### **New directions 7BI and 7BJ of the 2013 Directions**

5. After direction 7BH of the 2013 Directions, insert the following directions—

#### **“Smoking Cessation Service: general matters and preconditions to making arrangements**

**7BI.**—(1) The NHSCB must make arrangements for the provision of a service as part of the SCS with any pharmacy contractor (P) who—

- (a) meets the requirements set out in paragraphs (3) to (9); and
- (b) wishes to enter into such arrangements or is required to do so by virtue of regulation 66 of the Pharmaceutical Services Regulations (conditions relating to providing directed services).

(2) The underlying purposes of the SCS are to provide patients, referred on discharge from hospital by NHS trusts or NHS foundation trusts to community pharmacies, with medication and support to continue their smoking cessation treatment, with the aim of reducing morbidity and mortality from smoking and reducing health inequalities associated with higher rates of smoking.

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(a) The service specification for the Smoking Cessation Service is published on [www.nhsbsa.nhs.uk](http://www.nhsbsa.nhs.uk) and has the NHS England and NHS Improvement Publication Approval Reference: PAR1298.

(b) Signed on 30th September 2021.

(c) Inserted by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) Directions 2021, signed on 29th March 2021, and amended by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Further Amendments) (England) Directions 2021, signed on 30th September 2021.

(d) Substituted by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Further Amendments) (England) Directions 2021, signed on 30th September 2021.

(e) Relevant amendments were made by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) Directions 2021, signed on 29th March 2021 and the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Further Amendments) (England) Directions 2021, signed on 30 September 2021.

(3) P must be satisfactorily complying with P's obligations under Schedule 4 to the Pharmaceutical Services Regulations (Terms of service of NHS pharmacists) in respect of the provision of essential services and an acceptable system of clinical governance.

(4) In advance of providing the service, P must notify the NHSCB of P's intention to provide the service by completion of an electronic registration declaration on the NHS BSA Manage Your Service platform on the NHS BSA website.

(5) P must ensure that pharmacists providing the service are appropriately trained and competent to do so, as provided for in section 3 of the SCS service specification.

(6) P must be able to ensure, where possible, that referrals as part of the SCS, via the secure electronic system used for such referrals, can be received at the pharmacy throughout the pharmacy's core and supplementary opening hours.

(7) P must have in place at the pharmacy premises at or from which the service is to be provided standard operating procedures covering provision of the service, with which all pharmacy staff who are to be involved in the service are to be familiar, and which are to include—

- (a) key contact details;
- (b) equipment validation, maintenance and infection prevention and control measures (as per manufacturer's instructions and in line with current infection prevention and control guidance); and
- (c) signposting of locally commissioned smoking cessation services.

(8) P must have a room for confidential consultations at P's pharmacy premises available for use for the provision of the service (notwithstanding that it may be provided remotely, if that is agreed with the patient), which meets the applicable requirements of the Pharmaceutical Services Regulations.

(9) P must have a working carbon monoxide monitor that meets the requirements of the SCS service specification, and sufficient disposable mouthpieces to meet the likely demand for the service when providing it via face to face consultations at the pharmacy.

### **Smoking Cessation Service: ongoing conditions of arrangements**

**7BJ.**—(1) The NHSCB must ensure that arrangements pursuant to direction 7BI(1) with a pharmacy contractor (P) include terms equivalent to the requirements set out in this direction.

(2) P must comply, and must ensure that their pharmacy staff comply, with the requirements of the SCS service specification, in particular in respect of—

- (a) the inclusion and exclusion criteria in respect of people who are to be offered, or not offered, the service;
- (b) the signposting of people excluded from the service to other services;
- (c) the taking of referrals of patients from hospitals via a secure electronic referral;
- (d) contacting the patients referred to them, and dealing with cases where the patient cannot be contacted, declines the service or needs to be referred to a different NHS pharmacist or another smoking cessation service provider;
- (e) where the patient consents to receiving the service, conducting the initial consultation, following the consultation structure within the NCSCT Standard Treatment Programme, and including where appropriate—
  - (i) undertaking a CO test,
  - (ii) provision of behavioural support, and
  - (iii) the provision of Nicotine Replacement Therapy (NRT) in accordance with the arrangements made at the hospital (a maximum of two weeks NRT is to be supplied at any one time, for a course length not exceeding 12 weeks from the defined quit date, and the products supplied must be on the list of the GSL

NRT products which may be supplied as part of the service that is published in the Drug Tariff);

- (f) agreeing and undertaking a follow-up appointment cycle to monitor progress and provide support (interim appointments are to be no more than two weeks apart and timed to ensure supply of NRT does not run out on the day of the appointment);
- (g) agreeing and undertaking the formal reviews at four and twelve weeks after the defined quit date;
- (h) patients not continuing with the service, including in respect of re-engagement with the patient and signposting them to locally commissioned services;
- (i) ongoing support for the patients between the two formal reviews, if theirs is a successful quit as defined in the SCS service specification, including the provision of NRT as required;
- (j) communication with the patient's GP (if the patient has one) and the referring NHS Trust or NHS foundation trust, and reporting to the NHS BSA (including for payment and service evaluation purposes(a)); and
- (k) record keeping and data and information management, including compliance with the Records Management Code of Practice for Health and Social Care(b).

(3) P must ensure that the service is only provided by pharmacists, and all pharmacists providing the service must be appropriately trained and competent to do so, as provided for in section 3 of the SCS service specification.

(4) P must be able to ensure, where possible, that referrals as part of the SCS, via the secure electronic system used for such referrals, can be received at the pharmacy throughout the pharmacy's core and supplementary opening hours.

(5) P must have in place and keep updated at the pharmacy premises at or from which the service is to be provided standard operating procedures covering provision of the service, with which all pharmacy staff who are to be involved in the service are to be familiar, and which are to include—

- (a) key contact details;
- (b) equipment validation, maintenance and infection prevention and control measures (as per manufacturer's instructions and in line with current infection prevention and control guidance); and
- (c) signposting of locally commissioned smoking cessation services,

and P must review these procedures regularly or following any significant incident or change to the service.

(6) P must have a room for confidential consultations at P's pharmacy premises available for use for the provision of the service (notwithstanding that it may be provided remotely, if that is agreed with the patient), which meets the applicable requirements of the Pharmaceutical Services Regulations.

(7) P must ensure that remote consultations with the patient take place in circumstances where the conversation cannot be overheard, except by someone whom the patient wants to hear the conversation (for example, a carer).

(8) P must at all times have a working carbon monoxide monitor that meets the requirements of the SCS service specification, and sufficient disposable mouthpieces to meet the likely demand for the service when providing it via face to face consultations at the pharmacy.

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(a) The service specification requires data to be collected automatically via an application programme interface (API) for the service, but the obligations that arise in relation to the API are contingent on it being in operation.

(b) Published at: <https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-and-social-care>.

(9) P must ensure that patient safety incidents arising in the course of the provision of the service are reported in accordance with the clinical governance approved particulars provided for by paragraph 28 of Schedule 4 to the Pharmaceutical Services Regulations.

(10) P must ensure that the service is accessible, appropriate and sensitive to the needs of all service users, and that no eligible patient is excluded, or experiences difficulty in accessing or using the service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.

(11) If P is to cease providing the service permanently, P must do so in the manner provided for in the SCS service specification.”.

Signed by authority of the Secretary of State for Health and Social Care

A handwritten signature in purple ink that reads "Alette Addison" followed by a horizontal line.

*Alette Addison*  
Deputy Director Pharmacy, Dentistry and Eye Care  
Department of Health and Social Care

9th March 2022