THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (NHS Pharmacy Contraception Service and Other Amendments) (England) Directions 2023

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

Citation, commencement, extent, application and interpretation

1.—(1) These Directions may be cited as the Pharmaceutical Services (NHS Pharmacy Contraception Service and Other Amendments) (England) Directions 2023.

(2) As regards the commencement of these Directions-

- (a) directions 3 and 4 come into force on 15 May 2023; and
- (b) this direction and directions 2 and 5 come into force on 24 April 2023.
- (3) These Directions extend to England and Wales but apply only to England.

(4) In these Directions, "the 2013 Directions" means the Pharmaceutical Services (Advanced and Enhanced Services) Directions 2013(b).

⁽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; the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Further Amendments) (England) Directions 2021, signed on 30th September 2021; the Pharmaceutical Services (Smoking Cessation Service) (England) Directions 2022, signed on 9th March 2022; the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendment) Directions 2022, signed on 5th April 2022; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Further Amendments) Directions 2022, signed on 24th August 2022 and the Pharmaceutical Services (Advanced and Enhanced Services) (Amendment) (England) Directions; signed on 28th March 2023.

Amendment of direction 2 of the 2013 Directions

2. In direction 2 of the 2013 Directions (interpretation), at the appropriate places in the alphabetical order insert—

""NHS Pharmacy Contraception Service" means the NHS Pharmacy Contraception Service Advanced Service described in direction 7BK(2);";

""NHSPCS" means the NHS Pharmacy Contraception Service;"; and

""NHSPCS service specification" means the service specification for Tier 1 of the NHSPCS, which relates to the ongoing supply of oral contraception, produced by NHS England, published on 10 January 2023 and updated on 27 March 2023(**a**);".

Amendment of direction 7BA of the 2013 Directions

3.—(1) Direction 7BA of the 2013 Directions (NHS Community Pharmacist Consultation Service: general matters and preconditions to making arrangements) (**b**) is amended as follows.

(2) In paragraph (2), for "via the NHS 111 service, an IUC CAS or a GP surgery" substitute "via the NHS 111 service, an IUC CAS, a GP surgery, 999 services and providers of urgent and emergency care who are authorised by NHS England to provide this (for example, Urgent Treatment or Urgent Care Centres, an Emergency Department or an Accident and Emergency Unit)".

Amendment of direction 7BB of the 2013 Directions

4.—(1) Direction 7BB of the 2013 Directions (NHS Community Pharmacist Consultation Service: ongoing conditions of arrangements) (\mathbf{c}) is amended as follows.

(2) In paragraph (2), in sub-paragraphs (a), (b), (f) and (g), for "via the NHS 111 service, and IUC CAS or a GP surgery" substitute "via the NHS 111 service, an IUC CAS, a GP surgery, 999 services and providers of urgent and emergency care who are authorised by NHS England to provide this (for example, Urgent Treatment or Urgent Care Centres, an Emergency Department or an Accident and Emergency Unit)".

(3) In paragraph (5), for sub-paragraph (b) substitute—

"(b) the relevant bodies and services are informed to prevent them making any further referrals, as provided for in the CPCS service specification.".

New directions 7BK and 7BL of the 2013 Directions

5. After direction 7BJ of the 2013 Directions(d) (Smoking Cessation Service: ongoing conditions of arrangements), insert the following directions—

"NHS Pharmacy Contraception Service: general matters and preconditions to making arrangements

7BK.—(1) NHS England must make arrangements for the provision of a service as part of the NHS Pharmacy Contraception Service Advanced Service with any pharmacy contractor (P) who—

⁽a) The service specification is published on www.england.nhs.uk/long-read/nhs-pharmacy-contraception-service-tier-1 ongoing-supply of oral-contraception and has the NHS England Publication Approval Reference: PRN00019.

⁽b) Inserted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No.4) Directions 2019, signed on 25th October 2019, and amended by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) (No.2) Directions 2020, signed on 28th August 2020.

⁽c) Inserted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No.4) Directions 2019, signed on 25th October 2019, and amended by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) (No.2) Directions 2020, signed on 28th August 2020.

⁽d) Inserted by the Pharmaceutical Services (Smoking Cessation Service) (England) Directions 2022, signed on 9th March 2022.

- (a) meets the requirements set out in paragraphs (3) to (8); 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 purpose of the NHSPCS is to offer greater choice of where people can access contraception services, and in particular, as regards Tier 1 of the NHSPCS—

- (a) to provide a model for community pharmacy teams to continue the provision of oral contraception supplies initiated in primary care or sexual health clinics using a patient group direction to support the review and supply process; and
- (b) to establish an integrated pathway between NHS services to allow people greater choice and access when considering continuing their current form of oral contraception.

(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 NHS England 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 all pharmacy staff providing the service are appropriately trained and competent to do so, as provided for in section 5 of the NHSPCS service specification.

(6) P must—

- (a) have standard operating procedures in place covering the provision of the service that cover the matters specified in Section 3.5 of the NHSPCS service specification, and must have in place arrangements for regularly reviewing those procedures; and
- (b) have arrangements in place to ensure that all pharmacy staff involved in the provision of the service are familiar with those procedures.

(7) As regards premises-

- (a) P must have a room for confidential consultations at P's pharmacy premises available for use for the provision of the service which meets the applicable requirements of the Pharmaceutical Services Regulations; and
- (b) in all cases, where remote access to the service is preferred by the patient, P must have arrangements in place at P's premises which enable a person providing the service to communicate securely and confidentially via live video or audio link with the patient.
- (8) As regards equipment, P must have—
 - (a) the equipment for blood pressure readings and body mass index readings that is required by the NHSPCS service specification for delivery of the service; and
 - (b) arrangements in place to meet the minimum digital requirements of the service as provided for in the NHSPCS service specification.

NHS Pharmacy Contraception Service: ongoing conditions of arrangements

7BL.—(1) NHS England must ensure that arrangements pursuant to direction 7BK(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 NHSPCS 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 taking of referrals of patients from other providers of NHS services (although the service may be offered directly to people self-referring, and this possibility may be highlighted to people presenting with prescriptions for oral contraception);
- (c) responding to requests from patients for the service and where appropriate referring them to alternative providers of a contraception service;
- (d) where the patient consents to receiving the service, conducting the consultation provided for in the NHSPCS service specification in the manner specified, including in respect of—
 - (i) assessing safeguarding issues,
 - (ii) discussing alternative forms of contraception,
 - (iii) body mass index and blood pressure tests, where appropriate,
 - (iv) compliance with the patient group direction in accordance with which the oral contraception may be supplied, and
 - (v) advice about information sharing;
- (e) outcomes of the consultation, including in respect of repeat supplies and what to do if supplying oral contraception is not clinically appropriate;
- (f) patient safety incidents;
- (g) communication with the patient's GP (if the patient has one and the patient consents to this);
- (h) record keeping and data and information management, including compliance with the Records Management Code of Practice for Health and Social Care(**a**); and
- (i) post payment verification, monitoring and service evaluation (including what is to be available for inspection if there is a site visit).

(3) P must ensure that the service is only provided by pharmacists, except that body mass index and blood pressure tests may be conducted by a suitably trained pharmacy technician.

(4) P must ensure that all pharmacy staff providing the service are appropriately trained and competent to do so, as provided for in section 5 of the NHSPCS service specification.

(5) P must-

- (a) have in place and keep updated, as well as regularly reviewing, standard operating procedures covering the provision of the service that cover the matters specified in Section 3.5 of the NHSPCS service specification; and
- (b) have arrangements in place to ensure that all pharmacy staff involved in the provision of the service are familiar with and adhere to those procedures.

(6) As regards premises-

- (a) P must have a room for confidential consultations at P's pharmacy premises available for use for the provision of the service which meets the applicable requirements of the Pharmaceutical Services Regulations; and
- (b) in all cases, where remote access to the service is preferred by the patient, P must have arrangements in place at P's premises which enable a person providing the service to communicate securely and confidentially via live video or audio link with the patient.
- (7) As regards equipment, P must have at all times when the service is provided—
 - (a) the equipment for blood pressure readings and body mass index readings that is required by the NHSPCS service specification for delivery of the service; and

⁽a) Published at: https://transform.england.nhs.uk/information-governance/guidance/records-management-code/ and has the NHS England Publication Approval Reference: PAR00019.

(b) arrangements in place to meet the minimum digital requirements of the service as provided for in the NHSPCS service specification.

(8) 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.

(9) If P is to cease providing the service permanently, P must do so in the manner provided for in the NHSPCS service specification.".

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

Alte Aelens.

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

17 April 2023