
DIRECTIONS

THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (No. 4) (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(a).

Citation, commencement, extent, application and interpretation

1.—(1) These Directions may be cited as the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (No. 4) (England) Directions 2023.

(2) These Directions come into force on 31st January 2024.

(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).

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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, and the Health and Care Act 2022 (c. 31) (“the 2022 Act”), Schedule 1, paragraph 1. Section 128 has been amended by the 2012 Act, Schedule 4, paragraph 65, and the 2022 Act, Schedule 1, paragraph 1.
- (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, the Pharmaceutical Services (Advanced and Enhanced Services) (Amendment) (England) Directions; signed on 28th March 2023; the Pharmaceutical Services (NHS Pharmacy Contraception Service and Other Amendments) (England) Directions 2023, signed on 17th April 2023; the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (England) Directions 2023, signed on 29th August 2023; the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (No. 2)

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—

““NHS PFS service specification” means the Community Pharmacy advanced service specification for the NHS Pharmacy First Service (including the service previously known as the NHS Community Pharmacist Consultation Service (CPCS)), published by NHS England(a);” and

““NHS Pharmacy First Service” means the NHS Pharmacy First Service advanced service, which is described in direction 7BO(2);”.

Omission of directions 7BA and 7BB of the 2013 Directions

3. Omit direction 7BA (Community Pharmacist Consultation Service: general matters and preconditions to making arrangements) and 7BB (Community Pharmacist Consultation Service: ongoing conditions of arrangements) of the 2013 Directions(b).

New directions 7BO and 7BP of the 2013 Directions

4. After direction 7BN (NHS LFD Tests Supply Service Advanced Service: ongoing conditions of arrangements)(c), insert—

“NHS Pharmacy First Service: general matters and preconditions to making arrangements

7BO.—(1) NHS England must make arrangements for the provision of an advanced service as part of the NHS Pharmacy First Service with any pharmacy contractor (P) who—

- (a) meets the requirements set out in paragraphs (3) to (12); 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 NHS Pharmacy First Service are—

- (a) to offer patients who contact the NHS in specified ways the opportunity to access appropriate urgent care services in a convenient and easily accessible community pharmacy setting, thereby freeing up clinical capacity in other services and settings; and
- (b) at or from a community pharmacy—
 - (i) to identify ways in which patients can self-manage their health more effectively, with the support of pharmacists at community pharmacies,
 - (ii) to provide urgent access for patients who are not registered with a general practitioner in England to treatment for low acuity minor illnesses,
 - (iii) to ensure equity of access to the emergency supply of prescription only medicines, regardless of a patient’s ability to pay for the requested medicine, and

(England) Directions 2023, signed on 3rd November 2023; and the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (No. 3) (England) Directions 2023, signed on 30th November 2023.

- (a) The services specification is published at www.england.nhs.uk and has the NHS England Publication Approval Reference: PRN00936.
- (b) Directions 7BA and 7BB were 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 (NHS Pharmacy Contraception Service and Other Amendments) (England) Directions 2023, signed on 17th April 2023.
- (c) Inserted by the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (No. 2) (England) Directions 2023, signed on 3rd November 2023.

(iv) to utilise the clinical skills of community pharmacy teams to complete episodes of care for patients,

thereby improving patient access and potentially displacing activity from general practice and urgent and emergency care settings.

(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) P must have notified NHS England of P's intention to provide the service by completing the registration declaration on the NHS BSA Manage Your Service platform.

(5) P must ensure that the pharmacy staff who are to provide the service are competent to do so, and that they have undergone appropriate training and are familiar with, to the extent necessary for any role that they may be asked to perform as part of the service—

(a) the use of an otoscope; and

(b) the clinical pathways, clinical protocols and patient group directions (PGDs) that are part of the service.

(6) P must have in place an IT system that meets the minimum digital requirements for the NHS Pharmacy First Service, as specified in the Community Pharmacy Clinical Services Standard that has been approved for use by NHS England^(a).

(7) P must have in place, at P's pharmacy premises, appropriate standard operating procedures for the service, which meet the relevant requirements of the NHS PFS service specification, and must include the service in P's business continuity plan.

(8) P must ensure that all pharmacy staff who are to be involved in the provision of the service are familiar with the standard operating procedures and the parts of the business continuity plan that relate to the service.

(9) P must be able to provide all elements of the service, except that if P's premises are distance selling premises, P need not be able to provide (and in due course must not provide) consultations for the Acute Otitis Media clinical pathway.

(10) 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 the NHS PFS service specification (including with regard to accessible IT equipment); and

(b) P must have arrangements in place at P's pharmacy premises for when P undertakes remote consultations, which must enable a person providing the service to communicate securely and confidentially via live video or audio link with the person receiving the service, and any live video link must be of sufficient quality to allow for appropriate clinical examination where this is required.

(11) If P's pharmacy premises are distance selling premises, P must have arrangements in place to ensure that, where the gateway point of one of the clinical pathways is crossed, P is able to undertake remote consultations for that clinical pathway via live video link rather than via an audio link, the exception being the Acute Otitis Media clinical pathway which P is not to provide.

(12) P must have at P's pharmacy premises, for all times for when the service is to be provided, an otoscope, unless those premises are distance selling premises.

(a) This is available at www.england.nhs.uk.

NHS Pharmacy First Service: ongoing conditions of arrangements

7BP.—(1) NHS England must ensure that arrangements pursuant to direction 7BO(1) with a pharmacy contractor (P) include terms equivalent to the requirements set out in this direction.

(2) P must comply with, and must ensure that P's pharmacy staff comply with, the requirements of the NHS PFS service specification, in particular in respect of—

- (a) referral to P's pharmacy premises (which is a necessary precondition for the urgent repeat medicines and appliances supply service pathway, and for the minor illness referral service pathway, but not for the clinical pathways consultations service pathway);
- (b) the response to be made to a referring organisation, where a referral is made;
- (c) proactive contact with a patient who has been referred to P, to the extent this is provided for in the PFS service specification;
- (d) closure of the referral, where no contact is made;
- (e) in the case of a referral for an urgent repeat medicines or appliances supply—
 - (i) the conduct of the interview with the patient,
 - (ii) dealing with instances where a prescription is available to the patient,
 - (iii) dealing with instances where the medicine or appliance is not in stock at the pharmacy premises,
 - (iv) dealing with instances where it is appropriate for a supply to be made of a medicine or appliance that is in stock at the pharmacy premises, including determining the appropriate quantity to supply and dealing with any access issues where the patient is unable to get to the pharmacy premises, and
 - (v) dealing with instances where it is not appropriate for a supply to be made of a medicine or appliance (for example because of legal restrictions or patient factors), including ensuring the patient or their representative is able to speak to another appropriate health care professional;
- (f) in the case of a referral that relates to a low acuity, minor illness—
 - (i) ensuring that any relevant 'red flags' such as symptoms associated with sepsis, meningitis or cancer are recognised and responded to as part of the delivery of the service,
 - (ii) identifying concurrent medication or medical conditions which may affect the treatment of the patient,
 - (iii) the outcome of the referral (for example, self care advice and the potential sale of an over the counter medicine or referral to a separately commissioned pharmaceutical service or another NHS service),
 - (iv) dealing with instances where the patient has used the same service more than twice within a month with the same symptoms, and
 - (v) onward referrals for urgent appointments (where the pharmacist needs additional advice or to refer the patient to a higher acuity care location);
- (g) in a case where a patient either is referred to (by one of the referring organisations permitted to make referrals), or presents at or contacts P's pharmacy premises with symptoms potentially consistent with one of the conditions for which a clinical pathways consultation is potentially available—
 - (i) which are clinical pathways that (at the time of the referral or when the patient presents at or contacts P's pharmacy premises) are part of clinical pathways

consultations service pathway, which are established by reference to the NHS England's website^(a),

- (ii) when the gateway point for one of the clinical pathways is crossed (a clinical pathways consultation may only be provided if, in the case of a particular patient, it is crossed),
 - (iii) confirming the patient's allergy status and identifying any concurrent medication or medical conditions that may affect the treatment of the patient, and
 - (iv) the outcome of the referral (for example, self care advice and the potential sale of an over the counter medicine, the potential supply of an NHS medicine or referral to a separately commissioned pharmaceutical service or another NHS service);
- (h) dealing with potential safeguarding issues;
 - (i) consulting clinical records;
 - (j) obtaining and recording patient consent to receive the service;
 - (k) record keeping, and data and information management, including the requirements in respect of—
 - (i) the sharing of information with NHS England for the purposes of service monitoring and evaluation (including any additional reports that a pharmacy is required to provide for service evaluation),
 - (ii) the sharing of information with NHS BSA and NHS England for the purposes of ensuring compliance with the service particulars, and for post-payment verification and contract management, and
 - (iii) managing occasions when the Pharmacy First IT system is unavailable (including when to notify NHS England or P's integrated care board of the issue);
 - (l) the collection of prescription charges (where NHS medicines or appliances are supplied) and establishing and recording prescription charge exemption status;
 - (m) the timing of any supply of NHS medicines or appliances and the choice of which NHS medicines or appliances to supply;
 - (n) the records to be kept of the supply of NHS medicines or appliances;
 - (o) post event messaging to the patient's general practitioner (if the patient is registered with one), including what is to happen if there are problems with the relevant electronic systems for such messaging;
 - (p) the reporting of patient safety incidents; and
 - (q) post payment verification.

(3) P must ensure that the pharmacy staff who are providing the service are competent to do so, and that they have undergone appropriate training and are familiar with, to the extent necessary for any role that they may be asked to perform as part of the service—

- (a) the use of an otoscope; and
- (b) the clinical pathways, clinical protocols and patient group directions (PGDs) that are part of the service,

and P must keep records that are sufficient to demonstrate that P's pharmacy staff who are providing the service are competent to do so and have remained up to date with regard to the specific skills and knowledge that they need for any role that they may be asked to perform as part of the service.

(a) This is available at www.england.nhs.uk.

(4) P must have in place, use and keep updated an IT system that meets the minimum digital requirements for the NHS Pharmacy First Service, as specified in the Community Pharmacy Clinical Services Standard that has been approved for use by NHS England^(a).

(5) P must have in place and keep under review, at P's pharmacy premises, appropriate standard operating procedures for the service, which meet the relevant requirements of the NHS PFS service specification, and P must—

- (a) have included the service in P's business continuity plan; and
- (b) keep under review the arrangements that P has included for the service in P's business continuity plan.

(6) If P's pharmacy premises are distance selling premises, P must not provide clinical pathway consultations to persons who are present at (which includes in the vicinity of) those pharmacy premises.

(7) P must be able to provide, and must provide, all elements of the service, except that if P's premises are distance selling premises, P need not be able to provide, and must not provide, consultations for the Acute Otitis Media clinical pathway.

(8) 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 the NHS PFS service specification (including with regard to accessible IT equipment); and
- (b) P must have arrangements in place at P's premises for when P undertakes remote consultations, which must enable a person providing the service to communicate securely and confidentially via live video or audio link with the person receiving the service, and any live video link must be of sufficient quality to allow for appropriate clinical examination where this is required.

(9) Where clinical examination is required, P must ensure that any such examinations undertaken as part of a remote examination are only undertaken using a live video link which is, at the material time, of a quality that allows for appropriate examination (or must refer the patient elsewhere).

(10) Beyond the gateway point, P must only undertake remote consultations for the clinical pathways via video link, the exception being the Acute Otitis Media clinical pathway which must not be undertaken remotely.

(11) P must have, at P's pharmacy premises, at all times for when the service is provided, an otoscope, unless those premises are distance selling premises.

(12) P must ensure, in so far as is practicable, that the service is available at P's pharmacy premises throughout its core and supplementary opening hours (as defined in the Pharmaceutical Services Regulations), and must check, with appropriate regularity and when the pharmacy opens and closes, P's Pharmacy First IT system (including the pharmacy's shared NHSmail) in order to pick up referrals in a timely manner and ensure that no relevant messages (to the delivery of the service) are missed.

(13) P must ensure the service is accessible, appropriate and sensitive to the needs of all service users, and that no eligible patient is excluded or experiences particular 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.

(14) Where requested to do so, P must participate in any local audit of integrated service provision that is organised by NHS 111 or an NHS commissioner of NHS urgent or emergency care services for any area in which P's pharmacy premises are located or for which P's pharmacy premises provides the service.

(a) This is available at www.england.nhs.uk.

(15) NHS England must be able to withdraw all or any part of the service, and where NHS England does withdraw all or any part of the service, in accordance with the NHS PFS service specification, P must cease to provide that part or the service, whichever is withdrawn, at the point of the withdrawal.

(16) NHS England must be able to suspend P's participation in the service, and where NHS England does suspend P's participation in the service, in accordance with the NHS PFS service specification, P must not provide the service during the period of the suspension.

(17) If P wishes to stop providing the service, P must give notice of doing so in the manner provided for in the NHS PFS service specification.”.

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

A handwritten signature in dark ink, reading "Alette Addison" with a long horizontal flourish extending to the right.

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

19 December 2023