
DIRECTIONS

THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (No. 2) (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. 2) (England) Directions 2023.

(2) These Directions come into force on 6th November 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).

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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; 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; and the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (England) Directions 2023, signed on 29th August 2023.

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 LFD tests supply service” means the NHS Lateral Flow Device (LFD) tests supply service for patients potentially eligible for COVID-19 treatments advanced service, which is described in direction 7BM(2);” and

““NHS LFDTSS service specification” means the service specification for the NHS LFD tests supply service, published NHS England(a);”.

New directions 7BM and 7BN of the 2013 Directions

3. After direction 7BL (NHS Pharmacy Contraception Service: ongoing conditions of arrangements), insert—

“NHS LFD Tests Supply Service Advanced Service: general matters and preconditions to making arrangements

7BM.—(1) NHS England must make arrangements for the provision of a service as part of the NHS LFD tests supply service with any pharmacy contractor (P) who—

- (a) meets the requirements set out in paragraphs (3) to (5); 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 NHS LFD tests supply service is to offer at risk patients LFD tests to enable testing at home for COVID-19, following symptoms of infection, with a view to informing clinical assessments of whether a patient is suitable for and will benefit from National Institute for Health and Care Excellence recommended COVID-19 treatments.

(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 have in place, at P’s pharmacy premises, appropriate standard operating procedures for the service (which may be available electronically), having regard to the requirements of the National NHS LFDTSS service specification, about which staff (if there is any role that they may be asked to perform as part of the service) have received appropriate training and which include procedures in respect of—

- (a) reporting any patient safety incidents in line with the Approved Particulars for Patient Safety for pharmacies(b); and
- (b) liaison with other pharmacy contractors, in the event of P having no stock of COVID-19 lateral flow device tests, to support patients and their representatives being able to obtain tests elsewhere.

NHS LFD tests supply service: ongoing conditions of arrangements

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

(a) The services specification is published on www.england.nhs.uk and has the NHS England Publication Approval Reference: PRN00742.

(b) These are available on www.gov.uk.

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

- (a) the eligibility criteria for receiving COVID-19 lateral flow device tests as part of the service;
- (b) the arrangements for confirming eligibility by—
 - (i) seeing an NHS letter that confirms eligibility or confirming previous sight of such a letter (by accessing the pharmacy's own records), or
 - (ii) in the absence of such a letter, a pharmacist or pharmacy technician, on behalf of P, satisfying themselves that the patient has a qualifying condition by virtue of having at least one risk factor for progressing to severe COVID-19, as set out in the relevant National Institute for Health and Care Excellence Guidelines for the use of casirivimab plus imdevimab, nirmatrelvir plus ritonavir, sotrovimab and tocilizumab for treating COVID-19(a);
- (c) the volume of COVID-19 lateral flow device tests to be supplied (there is a limit of one box of 5 tests per consultation);
- (d) 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, and
 - (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
- (e) the keeping of records in respect of purchases of COVID-19 lateral flow device tests.

(3) P must have in place and keep under review at P's pharmacy premises appropriate standard operating procedures for the service (which may be available electronically), as described in direction 7BM(5), about which staff (if there is any role that they may be asked to perform as part of the service) must receive appropriate training.

(4) 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).

(5) 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.

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

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



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03 November 2023