
DIRECTIONS

THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) Directions 2021

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 and Emergency Declaration) (England) (Amendment) Directions 2021.

(2) These Directions come into force immediately after they are signed.

(3) These Directions extend to England and Wales but apply in relation to England only.

(4) In these Directions—

“the 2013 Directions” means the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013(b); and

“the Emergency Declaration Directions” means the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) Directions 2020(c).

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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 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; 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) (Amendment) (No. 2) (England) Directions 2020, signed on 28th August 2020; and the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Amendment) (No. 3) (England) Directions 2020, signed on 27th November 2020.
- (c) Signed on 27th March 2020. A relevant amendment was made to these Directions by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Amendment) (No. 3) (England) Directions 2020, signed on 27th November 2020.

Amendment of the Emergency Declaration Directions

2. In direction 2 of the Emergency Declaration Directions (declaration of emergency requiring the flexible provision of pharmaceutical services), for “31st March 2021” substitute “30th June 2021”.

Amendment of direction 2 of the 2013 Directions

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

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

““CPCLFDDS” means the Community Pharmacy COVID-19 Lateral Flow Device Distribution Service, which is the advanced service described in direction 7BE(2);”;

““CPCLFDDS service specification” means the service specification for the CPCLFDDS, produced by the NHSCB, which is dated 29th March 2021(a);”;

““LFD” means a lateral flow device test kit for COVID-19 lateral flow antigen tests;”.

New directions 7BE and 7BF of the 2013 Directions

4. After direction 7BD of the 2013 Directions(b) (NHS Community Pharmacy Hepatitis C Antibody Testing Service: ongoing conditions of arrangements), insert the following directions—

“Community Pharmacy COVID-19 Lateral Flow Device Distribution Service: general matters and preconditions to making arrangements

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

- (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 CPCLFDDS is to improve access to COVID-19 testing by making LFDs readily available from community pharmacies for distribution to asymptomatic patients.

(3) P must register to provide the service through the NHS BSA Manage Your Service platform on the NHS BSA website.

(4) 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.

(5) P must have in place at the pharmacy premises at or from which the service is to be provided standard operating procedures for the provision of the service with which all pharmacy staff, including locums, who are to be involved in the provision of the service are to be familiar.

(6) All pharmacy staff, including locums, at pharmacy premises at or from which the service is to be provided, who are to be involved in the provision of the service, must be competent to be so involved.

(7) P must have a suitable place, away from members of the public, to store LFD boxes that are to be provided as part of the service.

(8) P must ensure that P’s contact details, including the address of P’s pharmacy premises, are uploaded onto the NHS Test Finder service, so that those details are accessible via the

(a) The NHS Publishing Reference for the Lateral Flow Device Distribution Service is: C1181.

(b) Direction 7BD was inserted by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Amendment) (No. 2) (England) Directions 2020, signed on 28th August 2020.

119 telephone service and via the application and website designated by the NHSCB for use by the public for finding the CPCLFDDS(a).

Community Pharmacy COVID-19 Lateral Flow Device Distribution Service: ongoing conditions of arrangements

7BF.—(1) The NHSCB must ensure that arrangements pursuant to direction 7BE(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 including locums comply, with the requirements of the CPCLFDDS service specification, in particular in respect of—

- (a) recording the lot numbers of LFD cartons delivered to the pharmacy premises (in accordance with product recall requirements), including in respect of the length of time for which that information is to be held;
- (b) the weekly order limit for LFD cartons;
- (c) storage of the LFD cartons;
- (d) the numbers of LFD boxes to be provided to a person requesting provision of the service, and any requirements in respect of whom those persons may be;
- (e) the information to be requested from a person who receives the service;
- (f) the weekly entry of information—
 - (i) about the LFD boxes P supplies as part of the service, and
 - (ii) obtained from a person who receives the service,onto the NHS BSA Manage Your Service platform on the NHS BSA website, including the timeframe within which information must be entered;
- (g) the information to be provided to a person who receives the service in respect of—
 - (i) the contents of the boxes being supplied and the purpose of the tests,
 - (ii) the reporting of results and the importance of doing so,
 - (iii) the implications of negative results, and
 - (iv) the recording of lot numbers of LFD cartons and reporting incidents in relation to LFDs;
- (h) advertising LFD product recalls;
- (i) ensuring that the documentation, including electronic documentation, that needs to be duly completed for P to be paid the due amount for the service, and for post payment verification processes, is duly completed and submitted;
- (j) the steps to be taken if P is having problems delivering the service; and
- (k) ensuring that the clinical governance requirements for the service are complied with.

(3) P must have in place and keep under review at the pharmacy premises at or from which the service is to be provided standard operating procedures for the provision of the service with which all pharmacy staff, including locums, who are to be involved in the provision of the service are to be familiar.

(4) P must ensure that all pharmacy staff, including locums, at pharmacy premises at or from which the service is to be provided, who are to be involved in the provision of the service, are competent to be so involved.

(5) P must have a suitable place, away from members of the public, to store LFD boxes that are to be provided as part of the service.

(6) P must ensure that P's contact details, including the address of P's pharmacy premises, are, and remain, uploaded onto the NHS Test Finder service, so that those details are

(a) See <https://find-covid-19-rapid-test-sites.maps.test-and-trace.nhs.uk/>.

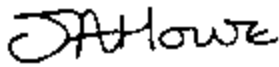
accessible via the 119 telephone service and via the application and website designated by the NHSCB for use by the public for finding the CPCLFDDS.

(7) P must ensure, in so far as is practicable, that the service is available at P's pharmacy premises at the times throughout its core opening hours and supplementary opening hours (as defined in the Pharmaceutical Services Regulations(a)).

(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 CPCLFDDS service specification.”.

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



29 March 2021

Jeannette Howe
Head of Pharmacy
Department of Health and Social Care

(a) See regulation 2(1) of those Regulations.