THE NATIONAL HEALTH SERVICE ACT 2006

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

The Secretary of State gives the following Directions in exercise of the powers conferred by sections 127, 128, 168A, 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 (Advanced and Enhanced Services and Emergency Declaration) (Further Amendments) (England) Directions 2021.

(2) These Directions come into force—

(a) in the case of this direction and directions 2 and 4, immediately after they are signed;

(b) in the case of direction 3(1) and (3) and 6, on 1st October 2021; and

(c) in the case of direction 3(2) and 5, on 4th October 2021.

(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**); and

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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. Section 168A was inserted by the 2012 Act, section 49(4). *See* regulation 2(5) of the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (S.I. 2013/349, as amended), which contains a definition of "emergency requiring the flexible provision of pharmaceutical services" which is relevant to the powers being exercised.

(**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

"the 2020 Directions" means the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) Directions 2020(**a**).

Amendment of the 2020 Directions

2. In direction 2 of the 2020 Directions(**b**) (declaration of emergency requiring the flexible provision of pharmaceutical services), for "30th September 2021" substitute "31st January 2022".

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 place in the alphabetical order insert—

""CPCLFDDS service specification" means the service specification for the CPCLFDDS, produced by the NHSCB, which is dated 31st August 2021(**c**);".

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

""CPHCFAS" means the Community Pharmacy Hypertension Case-Finding Advanced Service, which is the service described in direction 7BG(2);"; and

""CPHCFAS service specification" means the service specification for the CPHCFAS, produced by the NHSCB, published in September 2021(**d**);".

Amendment of directions 7A and 7B of the 2013 Directions

4.—(1) In direction 7A of the 2013 Directions(**e**) (Community Pharmacy Seasonal Influenza Vaccination Advanced Service: general matters and preconditions to making arrangements), in paragraph (4), omit ", pharmacy technician".

(2) In direction 7B of the 2013 Directions(**f**) (Community Pharmacy Seasonal Influenza Vaccination Advanced Service: ongoing conditions of arrangements)—

(a) from the second numbered paragraph (6) to the end of the direction, the sequence of paragraphs is renumbered paragraphs (8) to paragraph (16); and

(b) in paragraph (7)—

(i) in the stem, omit "pharmacy technician or",

(ii) in sub-paragraph (a), omit "or pharmacy technician," and ", pharmacy technician",

(iii) in sub-paragraph (b), omit ", pharmacy technician" at each place where it occurs (thrice),

(iv) in sub-paragraph (c), omit "or pharmacy technician,", and

(v) in sub-paragraph (d), omit "or pharmacy technician,".

Emergency Declaration) (Amendment) (England) Directions 2021, signed on 29th June 2021; and the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2021, signed on 1st September 2021.

(**a**) Signed on 27th March 2020. A relevant amendment is made in the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Amendment) (England) Directions 2021, signed on 29th June 2021.

(**b**) As amended by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Amendment) (England) Directions 2021, signed on 29th June 2021.

(**c**) The service specification for the Lateral Flow Device Distribution Service is published on www.nhsbsa.uk. The publication reference is: C1181.2.0.

(**d**) The service specification for the Community Pharmacy Hypertension Case-Finding Advanced Service is published on www.nhsbsa.nhsk.uk.

(**e**) As substituted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2021, signed on 1st September 2021.

(**f**) As substituted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2021, signed on 1st September 2021.

Amendment of direction 7BE of the 2013 Directions

5. In direction 7BE of the 2013 Directions(**a**) (Community Pharmacy COVID-19 Lateral Flow Device Distribution Service: general matters and preconditions to making arrangements)—

(a) omit ", including locums," at each place where it occurs (twice); and

(b) for paragraph (8) substitute the following paragraph—

"(8) P must ensure, in the manner provided for in the CPCLFDDS service specification, that P's contact details as a provider of the service are available to potential users of the service on an NHS website.".

Revised direction 7BF of the 2013 Directions

6. For direction 7BF of the 2013 Directions(**b**) (Community Pharmacy COVID-19 Lateral Flow Device Distribution Service: ongoing conditions of arrangements), substitute the following direction—

"**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 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, and stock and quality control, of the LFD cartons;

(d) the numbers of LFD boxes to be provided to a person requesting provision of the service (a maximum of two boxes per transaction, unless this is amended in accordance with the service specification);

(e) any requirements in respect of whom those persons may be (including in respect of the recommended minimum age for the collection of LFD boxes);

(f) the information to be requested from a person who receives the service, including the 16-digit collect code;

(g) encouraging the obtaining of 16-digit collect codes, and in respect of recording of any 16-digit collect codes supplied to P;

(h) the information to be recorded by P onto the NHS BSA Manage Your Service platform on the NHS BSA website in respect of each individual transaction, including anonymous collections, and in respect of how long P is to keep that information;

(i) the supply by P of additional information about anonymous collections, on request;

(j) the frequency of entry by P of information onto the NHS BSA Manage Your Service platform on the NHS BSA website, and in respect of the entry of nil returns;

(**a**) Inserted by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) Directions 2021, signed on 29th March 2021.

(**b**) Inserted by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) Directions 2021, signed on 29th March 2021.

(k) the information to be provided by P to a person who receives the service in respect of—

(i) the purpose of the test (and when instead to complete a PCR test),

(ii) the contents of the boxes being supplied,

(iii) the implications of negative results,

(iv) the implications of positive results and what to do in the event of one,

(v) the reporting of all results, and

(vi) the recording of lot numbers of LFD cartons and reporting incidents in relation to LFDs;

(l) advertising service availability;

(m) advertising and responding to LFD product recalls;

(n) 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;

(o) the steps to be taken if P is having problems delivering the service; and

(p) ensuring that the clinical governance requirements for the service are complied with; and

(q) the service evaluation requirements of the service.

(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 who are to be involved in the provision of the service are to be familiar.

(4) P must ensure that all pharmacy staff 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, in the manner provided for in the CPCLFDDS service specification, that P's contact details as a provider of the service are available to potential users of the service on an NHS website.

(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.".

New Directions 7BG and 7BH of the 2013 Directions

7. After direction 7BF of the 2013 Directions(**b**), insert the following directions—

(**a**) *See* regulation 2(1) of those Regulations.
(**b**) As substituted by these Directions.

"Community Pharmacy Hypertension Case-Finding Advanced Service: general matters and preconditions to making arrangements

7BF.—(1) The NHSCB must make arrangements for the provision of a service as part of the CPHCFAS 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 purposes of the CPHCFAS are—

(a) to identify people with high blood pressure who have previously not had a confirmed diagnosis of hypertension, and to refer them to a provider of primary medical services in order to confirm the diagnosis and for appropriate management of the condition;

(b) at the request of a provider of primary medical services, to undertake ad hoc clinic and ambulatory blood pressure measurements; and

(c) to promote healthy behaviours in the persons to whom the service is provided.

(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—

(a) notify the NHSCB of P's intention to provide the service by completion of the registration declaration on the NHS BSA Manage Your Service platform on the NHS BSA website; and

(b) engage with providers of primary medical services or Primary Care Networks (or where appropriate both) locally in order to make them aware of P's intention to participate in the service.

(5) All pharmacists providing the service must be appropriately trained and competent to do so, and in particular—

(a) must have completed the training provided by the equipment manufacturer on how to use the blood pressure monitoring equipment (if any);

(b) must have read and understood and be familiar with the operational processes in the CPHCFAS service specification; and

(c) must have read and understood and be familiar with NICE Guideline (NG 136) Hypertension in Adults: diagnosis and management(**a**).

(6) 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 requirements for such a room in the CPHCFAS service specification, in particular in respect of measuring blood pressure and access to IT equipment in order to make contemporaneous records (notwithstanding that the service specification permits aspects of the service to be provided elsewhere).

(7) P must have available for use as part of the service blood pressure monitors validated by the British and Irish Hypertension Society (as recommended by the National Institute for Health and Care Excellence).

(8) P must have in place at the pharmacy premises from which the service is to be provided standard operating procedures for the service—

(a) which include the processes for maintenance and validation of the equipment used in the course of providing the service; and

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(**a**) Available at www.nice.org.uk/guidance/ng136.

(b) with which all pharmacy staff who are to be involved in providing the service must be familiar.

Community Pharmacy Hypertension Case-Finding Advanced Service: ongoing conditions of arrangements

7BG.—(1) The NHSCB must ensure that arrangements pursuant to direction 7BF(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 CPHCFAS 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 identification of people to whom the service is to be provided (including by the use of promotional materials);

(c) the taking of referrals from providers of primary medical services (which may be for an initial consultation or for ambulatory blood pressure monitoring (ABPM) without an initial consultation);

(d) the initial consultation (where appropriate) at which, if the patient consents (and qualifies for the service), the patient's blood pressure is to be taken and the results discussed;

(e) the provision of information to the patient about the results at or after the initial consultation;

(f) the provision of information about the results to the patient's GP (if the patient has a GP);

(g) the next steps to be followed if either the systolic or diastolic measurements, or both, fall outside the normal range;

(h) the offer, in the circumstances provided for in the CPHCFAS, of ABPM;

(i) the loaning of ABPM devices, including where patients fail to attend appointments to borrow ABPM devices, and the follow-up action to be taken when ABPM devices are loaned;

(j) the return of ABPM devices;

(k) promoting healthy behaviours (including signposting to other services);

(l) recording the advice given to patients, and record management;

(m) 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; and

(n) the service evaluation requirements of the service.

(3) All pharmacists providing the service must be appropriately trained and competent to do so, and in particular—

(a) must have completed the training provided by the equipment manufacturer on how to use the blood pressure monitoring equipment (if any);

(b) must have read and understood and be familiar with the operational processes in the CPHCFAS service specification; and

(c) must have read and understood and be familiar with NICE Guideline (NG 136) Hypertension in Adults: diagnosis and management(**a**).

(4) P must have a room for confidential consultations at P's pharmacy premises for use in the provision of the service which meets the requirements for such a room in the CPHCFAS

(**a**) Available at www.nice.org.uk/guidance/ng136.

service specification, in particular in respect of measuring blood pressure and access to IT equipment in order to make contemporaneous records (notwithstanding that the service specification permits aspects of the service to be provided elsewhere).

(5) 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**)).

(6) P must only use, in the course of providing the service, blood pressure monitors validated by the British and Irish Hypertension Society (as recommended by the National Institute for Health and Care Excellence).

(7) P must ensure that all blood pressure monitors used in the course of providing the service are subject to—

(a) periodic validation, maintenance and recalibration; and

(b) infection control and cleaning measures,

in the manner provided for by the CPHCFAS service specification.

(8) P must have in place at the pharmacy premises from which the service is to be provided standard operating procedures for the service—

(a) which include the processes for maintenance, validation and recalibration of the equipment used in the course of providing the service; and

(b) with which all pharmacy staff who are to be involved in providing the service must be familiar,

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

(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 CPHCFAS service specification.".

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

Alette Addison
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Department of Health and Social Care

30th September 2021

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