THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2018

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, application and interpretation

1.—(1) These Directions may be cited as the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2018.

(2) These Directions come into force on 1st September 2018.

(3) These Directions apply in relation to England.

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

Amendment of direction 2 of the 2013 Directions

2. In direction 2 of the 2013 Directions (interpretation), for the definition of—

(a) "National PGD" substitute the following definition—

> ""National PGD" means the Patient Group Direction authorised by the NHSCB in respect of the administration of inactivated influenza vaccine to adults in accordance with the CPSIVAS and national influenza immunisation programme, which is valid from 1st September 2018 and has the published expiry date of 31st March 2019(**c**) (and which may be revised from time to time);"; and

(b) "CPSIVAS" substitute the following definition—

> ""CPSIVAS service specification" means the service specification for the CPSIVAS, produced by the NHSCB, which has the publication date of 20 August 2018(**d**);".

(**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; and the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2018, signed on 8th March 2018.

(**c**) NHS England Publications gateway reference 08379.

(**d**) NHS England Publications gateway reference 08291.

New directions 7A and 7B of the 2013 Directions

3. For directions 7A and 7B of the 2013 Directions (National Influenza Adult Vaccination Service: general matters and preconditions to making arrangements, and ongoing conditions for arrangements) substitute the following directions—

Community Pharmacy Seasonal Influenza Vaccination Advanced Service: general matters and preconditions to making arrangements

7A.—(1) Until the end of 31st March 2019, the NHSCB must make arrangements for the provision of a service as part of the CPSIVAS 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 CPSIVAS is to enable pharmacy contractors to participate in arrangements for the administration of inactivated influenza vaccine to patients in accordance with the National PGD, as part of the NHSCB, Public Health England and Department of Health and Social Care's annual flu programme(**a**).

(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) Any registered pharmacist who is to be involved in the administration of vaccines as part of the service (including locums) —

(a) must have been appropriately trained and be competent to do so, having regard to the requirements of the National PGD and the CPSIVAS service specification (including the relevant requirements of the National Minimum Standards(**b**) referred to in paragraph 4.6 of that specification); and

(b) must have completed the relevant Centre for Pharmacy Postgraduate Education declaration of competence(**c**), copies of which must be kept at P's pharmacy premises.

(5) Pharmacy staff at pharmacy premises at or from which the service is to be provided, if there is any role that they may be asked to perform as part of the service, must have been appropriately trained, having regard to requirements of the National PGD and the CPSIVAS service specification.

(6) P must have in place at the pharmacy premises at or from which the service is to be provided appropriate standard operating procedures for the service, having regard to the requirements of the National PGD and the CPSIVAS 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) cold chain integrity;

(b) needle stick injuries;

(c) advice to staff involved in the service in respect of vaccination against Hepatitis B;

(d) the identification and management of adverse reactions;

(e) the handling, removal and safe disposal of any clinical waste related to the provision of the service (whether the service is provided at the pharmacy premises or elsewhere); and

(**a**) Available at www.gov.uk/government/collections/annual-flu-programme.
(**b**) These are available at www.gov.uk/government/publications/immunisation-training-national-minimum-standards.
(**c**) This is available on the CPPE website, www.cppe.ac.uk.

(f) if vaccines are to be administered at a care home, or at a patient's home, performing that activity away from the pharmacy premises.

(7) If P is intending to administer vaccines at a care home or a patient's home as part of the CPSIVAS, P must notify the NHSCB before the first occasion on which P intends to do so in the manner provided for in the CPSIVAS service specification.

(8) P must be able to provide the services which are part of the CPSIVAS at an acceptable location, and for these purposes "acceptable location" means—

(a) a room for confidential consultations at P's pharmacy premises which meets the requirements for such a room in the CPSIVAS service specification;

(b) if, following notification to the NHSCB, P is to provide services as part of the CPSIVAS at a care home, a room at that care home which meets the requirements for such a room in the CPSIVAS service specification; or

(c) if, following notification to the NHSCB, P is to provide services as part of the CPSIVAS at a patient's home, a location in the patient's home that P considers suitable having regard to the standard operating procedures mentioned in paragraph (6).

Community Pharmacy Seasonal Influenza Vaccination Advanced Service: ongoing conditions of arrangements

7B.—(1) The NHSCB must ensure that arrangements pursuant to direction 7A(1) with a pharmacy contractor (P) include terms equivalent to the requirements set out in this direction.

(2) Inactivated influenza vaccines must only be administered under the arrangements in accordance with the National PGD, and this includes the requirements of the National PGD before and after administration of a vaccine.

(3) The only inactivated influenza vaccines to be administered under the arrangements must be those listed in the NHSCB, Public Health England and Department of Health and Social Care's annual flu programme(**a**).

(4) P must have in place and keep under review at the pharmacy premises at or from which the service is to be provided appropriate standard operating procedures for the service, as described in direction 7A(6), about which staff (if there is any role that they may be asked to perform as part of the service) have received appropriate training.

(5) Vaccines must only be administered under the arrangements by a registered pharmacist, and that registered pharmacist (including if he or she is a locum)—

(a) must have been appropriately trained and be competent to do so, having regard to the requirements of the National PGD and the CPSIVAS service specification (including the relevant requirements of the National Minimum Standards(**b**) referred to in paragraph 4.6 of that specification);

(b) must have completed the relevant Centre for Pharmacy Postgraduate Education declaration of competence(**c**), copies of which must be kept at P's pharmacy premises;

(c) must be authorised by name under the National PGD before working to it; and

(d) must adhere to—

(i) the National PGD,

(ii) the relevant requirements of the publication known as the Green Book(**d**), and,

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(**a**) Available at www.gov.uk/government/collections/annual-flu-programme.
(**b**) These are available at www.gov.uk/goverment/publications/immunisation-training-national minimum-standards.
(**c**) Available at www/cppe.ac.uk/services/docs/commissioners.
(**d**) Available at www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book.

(ii) as appropriate, to the standard operating procedures referred to in paragraph (4).

(6) P must only provide the service at an acceptable location, and for these purposes, "acceptable location" has the same meaning as in direction 7A(8).

(7) In respect of the first occasion on which P intends to administer vaccines at a care home or a patient's home as part of the CPSIVAS, P must notify the NHSCB of their intention to do so in the manner provided for in the CPSIVAS service specification.

(8) In respect of each occasion on which P intends to administer vaccines at a care home or a patient's home as part of the CPSIVAS (apart from sub-paragraph (a), which only applies where patients are being vaccinated in care homes)—

(a) P must ensure that each patient's general practitioner is made aware in advance of the vaccination that the patient will be vaccinated;

(b) P must ensure that appropriate arrangements are in place at the care home or the patient's home (having regard to the standard operating procedures mentioned in direction 7A(6)) for the handling, removal and safe disposal of any clinical waste related to the provision of the service;

(c) where vaccinations are administered at—

(i) a care home, P must ensure that vaccinations are only administered in a room which meets the requirements for such a room in the CPSIVAS service specification, or

(ii) a patient's home, P must ensure that vaccinations are only administered in a location which P considers suitable having regard to the standard operating procedures referred to in paragraph (4); and

(d) P must ensure that appropriate infection control is available at the care home or at the patient's home.

(9) P must ensure, in so far as is practicable, that services which are part of the arrangements are available and on offer at P's pharmacy premises throughout its core opening hours and supplementary opening hours (as defined in the Pharmaceutical Services Regulations(**a**)).

(10) 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 (subject to the requirements of the National PGD).

(11) P must ensure the patient's consent to the administration of the vaccine is recorded using the consent form in the CPSIVAS service specification, and information in the form must be shared on request with the NHSCB, where it is needed for assurance and post payment verification.

(12) P must ensure that each patient vaccinated under the arrangements, (or where appropriate his or her carer) must be asked to complete the patient questionnaire in the CPSIVAS service specification, and thereafter P must process the information contained in any completed patient questionnaires in the manner requested by the NHSCB.

(13) As regards each patient vaccinated under the arrangements who is registered with a general practitioner, P must ensure that the patient's general practitioner is notified, using the form for this purpose in the CPSIVAS service specification, in the manner provided for in that service specification.

(14) If —

(a) a patient vaccinated under the arrangements presents with an adverse drug reaction which is or may be linked to that vaccination; and

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(**a**) *See* regulation 2(1) of those Regulations for the relevant definitions.

(b) a pharmacist who is P or who is employed or engaged by P believes the adverse reaction is of clinical significance,

P or a person employed or engaged by P must ensure that, having managed the patient's condition appropriately, the patient's general practitioner and where appropriate the Medicines and Healthcare products Regulatory Agency (under the Yellow Card Scheme) are notified as soon as possible, in the manner provided for in the National PGD and the CPSIVAS service specification.

(15) P must keep a record of all patients receiving treatment under the arrangements—

(a) in the manner required and for the purposes specified in the National PGD and the CPSIVAS service specification, including the requirements relating to signature and dating by the immuniser and, in the case of electronic records, password protection; and

(b) for the purposes specified in the National PGD and the CPSIVAS service specification.

(16) NHSCB must terminate any arrangements that are entered into or still in force on 31st March 2019 with effect from the end of 31st March 2019.".

Amendment of direction 7C of the 2013 Directions

4. In direction 7C of the 2013 Directions (**a**) (Urgent Medicine Supply Advanced Service pilot scheme: general matters and preconditions to making arrangements), in paragraph (1) for "30th September 2018" substitute "31st March 2019".

Amendment of direction 7D of the 2013 Directions

5. In direction 7D of the 2013 Directions (**b**) (Urgent Medicine Supply Advanced Service pilot scheme: ongoing conditions of arrangements)—

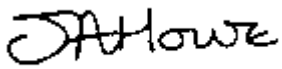
(a) in paragraph (2)(d) after "NHS summary care records" insert "during the telephone conversation with a patient, or if not done then, during the physical consultation with the patient, in the manner required by paragraphs 3.2.4 and 3.3.2 of the NUMAS service specification, including recording the reason for not doing so,"; and

(b) in paragraph (12), for "30th September 2018" substitute "31st March 2019".

Revocation of the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2017

6. The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2017(**c**) (new directions 7A and 7B of the 2013 Directions) is revoked.

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



Jeannette Howe
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Department of Health and Social Care

31st August 2018

(**a**) Direction 7C was inserted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No.2) Directions 2016, signed on 30th November 2016, and amended by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2018, signed on 8th March 2018.

(**b**) Direction 7D was inserted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No.2) Directions 2016, signed on 30th November 2016, and amended by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2018, signed on 8th March 2018.

(**c**) Signed on 29th August 2017.