D I R E C T I O N S

2021 No.

THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (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, application and interpretation

1.—(1) These Directions may be cited as the Pharmaceutical Services (Advanced and Enhanced Services) (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**).

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 place in the alphabetical order insert—

(**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; 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) (England) (Amendment) Directions 2021, signed on 9th March 2021; the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) Directions 2021, signed on 29th March 2021; and the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (Amendment) (England) Directions 2021, signed on 29th June 2021.

""the National Protocol" means the protocol under regulation 247A of the Human Medicines Regulations 2012(**a**) (protocols relating to coronavirus and influenza vaccinations and immunisations) that has been approved by or on behalf of the Secretary of State in respect of the administration of inactivated influenza vaccine in accordance with the national flu immunisation programme 2021/22, which is valid from 1st September 2021(**b**) (and which may be revised from time to time);";

(3) In the definition of "CPSIVAS service specification", for "August 2020" substitute "August 2021".

(4) For the definition of "National PGD"(**c**) substitute the following definition—

""National PGD" means the Patient Group Direction authorised by the NHSCB in respect of the administration of inactivated influenza vaccine in accordance with the CPSIVAS and the national flu immunisation programme 2021/22, which is valid from 1st September 2021 and has the published expiry date of 31st March 2022(**d**) (and which may be revised from time to time);".

Amendment of direction 6 of the 2013 Directions

3.—(1) Direction 6(**e**) (New Medicine Service: general matters and preconditions for making arrangements) is amended as follows.

(2) After paragraph (4) insert—

"(5) Any registered pharmacist who will provide the New Medicine Service must have the necessary knowledge and skills to do so, and must assess and declare their competence by completing the NHS self-assessment form (**f**) and by providing a completed copy of the form to P, and P must retain a copy of this form.".

(3) At the beginning of paragraph (9), for "Subject to paragraph (10)," substitute "Subject to paragraphs (10) and (11)," .

(4) In paragraph (10)—

(a) at the end of sub-paragraph (a), omit "and";

(b) at the end of sub-paragraph (b), insert "or"; and

(c) after sub-paragraph (b) insert—

"(c) where required, in a patient's home, provided P has ensured that appropriate safeguarding checks have been made in accordance with the service specification, and that if requested to do so, P provides the evidence of the safeguarding checks required under the service specification to NHSCB.".

(5) After paragraph (10), insert—

"(11) Paragraph (9) does not apply where P has been exempted from the requirement to have a consultation room at P's pharmacy pursuant to paragraphs 28A and 28B of Schedule 4 to the Pharmaceutical Services Regulations, in which case P may provide the service remotely or at a patient's home but must nevertheless ensure that P has arrangements in place at those premises which enable a person providing the New Medicine Service to communicate confidentially with a person accessing that service by—

(a) telephone or another live audio link, and

(b) via a live video link.".

(**a**) S.I. 2012/1916; regulation 247A was inserted by S.I. 2020/1125.
(**b**) Approved but at time of signature not yet published on gov.uk.
(**c**) As substituted by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) (No.2) Directions 2020, signed on 28th August 2020..
(**d**) Template published on gov.uk. PHE gateway number GOV-9226.
(**e**) Relevant amendments are made by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) (No.2) Directions 2020 signed on 28th August 2020.
(**f**) The form can be downloaded from psnc.org.uk/nms.

Amendment of direction 7 of the 2013 Directions

4. In direction 7 (New Medicine Service: ongoing conditions of arrangements), in paragraph (1)(**a**)—

(a) for sub-paragraph (a), substitute—

"(a) any registered pharmacist who will provide the New Medicine Service must have the necessary knowledge and skills to do so, and must assess and declare their competence by completing the NHS self-assessment form (**b**) and by providing a completed copy of the form to P, and P must retain a copy of this form;";

(b) in sub-paragraph (b), after "at P's pharmacy premises," insert "(unless P has been exempted from the requirement to have a consultation room at P's pharmacy pursuant to paragraphs 28A and 28B of Schedule 4 to the Pharmaceutical Services Regulations, in which case P may provide the service remotely or at a patient's home),";

(c) in sub-paragraph (c)—

(i) at the end of paragraph (i), omit "and";

(ii) at the end of paragraph (ii), insert "or"; and

(iii) after paragraph (ii) insert—

"(iii) where required, in a patient's home, provided P has ensured that appropriate safeguarding checks have been made in accordance with the service specification, and that if requested to do so, P provides the evidence of the safeguarding checks required under the service specification to NHSCB.";

(d) in sub-paragraph (f), for "where clinically appropriate, and with the prior agreement of the patient, provided from another location by P by telephone or by video link", substitute "where clinically appropriate, and with the prior agreement of the patient, provided from another location by P by telephone or by video link, or if required at a patient's home, subject to the requirements set out in sub-paragraph (c)"; and

(e) after sub-paragraph (n), insert—

"(o) between 1st September 2021 and 31st March 2022, catch up reviews may be provided by P to eligible patients who meet the criteria set out in the service specification and who have missed a review due to the coronavirus pandemic as part of the New Medicine Service;

(p) where P provides catch up reviews, P must do so in accordance with the service specification, and in particular—

(i) though catch up reviews will ordinarily follow the standard New Medicine Service approach, as set out above, patient engagement and intervention stages of the New Medicine Service review may occur simultaneously at the point at which the patient is identified or contacted by P (which could be following a review of the pharmacy's patients by P or when the patient's medication is next dispensed at or from the pharmacy), or may vary from the standard approach, in accordance with the service specification, where patients have started taking the new medicines and have been established on the new medicine for a period of months,

(ii) if it is identified during the intervention stage that the patient has no issues with the prescribed medication requiring further review or support, P can use their professional judgement and not undertake the follow up review stage,

(iii) if P, following the delivery of the intervention stage, does not identify any issues requiring the follow up stage, P must provide clinical advice to support

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(**a**) Relevant amendments are made by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) (No.2) Directions 2020 signed on 28th August 2020.

(**b**) The form can be downloaded from psnc.org.uk/nms.

the patient as required and close the New Medicine Service review process, and must record this in the pharmacy record, and

(iv) if it is identified that the patient does not require a follow up review and the New Medicine Service is concluded after completion of the intervention stage, this is to be treated as if P had completed a full New Medicine Service review.".

Substitution of direction 7A and 7B of the 2013 Directions

5.For directions 7A and 7B of the 2013 Directions (**a**) (Community Pharmacy Seasonal Influenza Vaccination Advanced Service: general matters and preconditions to making arrangements), substitute—

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

7A.—(1) Until the end of 31st March 2022, 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 (7); 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 or the National Protocol, as part of the NHSCB, Public Health England and Department of Health and Social Care's national flu immunisation programme 2021 to 2022(**b**).

(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 pharmacist, pharmacy technician or other authorised person who is to be involved in the administration of vaccines as part of the service must have been appropriately trained and be competent to do so, having regard to the requirements of the National PGD, the National Protocol and the CPSIVAS service specification (including the relevant requirements of the National Minimum Standards(**c**) referred to in paragraph 4.5 of that specification), and to any JCVI guidance on the required interval between, or the co-administration of, vaccinations under this service and other vaccination types.

(5) Pharmacy staff or other persons 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, the National Protocol and the CPSIVAS service specification, and to any JCVI guidance on the required interval between, or the co-administration of, vaccinations under this service and other vaccination types.

(6) P must have in place at the pharmacy premises, or any other premises or sites from which the service is to be provided, appropriate standard operating procedures for the service (which may be available electronically), having regard to the requirements of the National PGD, the National Protocol and the CPSIVAS service specification, and to any JCVI guidance on the required interval between, or the co-administration of, vaccinations under this service and other vaccination types, about which staff (if there is any role that

(**a**) As substituted by the Pharmaceutical Services (Advanced and Enhanced Services and Emergency Declaration) (England) (Amendment) (No.2) Directions 2020, signed on 28th August 2020.
(**b**) See the letters published on gov.uk with PHE publications gateway number GW-1266 and 2020153.
(**c**) These are available at www.gov.uk/government/publications/immunisation-training-national-minimum-standards.

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

(f) performing that activity away from the pharmacy premises.

(7) 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, or, as part of measures put in place to assist in the handling of a pandemic, at any other location at P's pharmacy that P considers suitable having regard to the standard operating procedures mentioned in paragraph (6);

(b) where the service is being provided at a premises or site other than P's pharmacy premises, such as a village hall, place of worship, mobile vaccination van or other location or site, a location or site which in the clinical judgement of P is considered to be suitable for the provision of the service, having regard to the standard operating procedures mentioned in paragraph (6) and which meet the professional standards required by the General Pharmaceutical Council and the CPSIVAS service specifications;

(c) if P is to provide services as part of the CPSIVAS at a care home, a room or any other location in the home that P considers suitable having regard to the standard operating procedures mentioned in paragraph (6); or

(d) if 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 or the National Protocol, and this includes the requirements of the National PGD or the National Protocol before and after administration of a vaccine, and in line with any JCVI guidance on the required interval between, or the co-administration of, vaccinations under this service and other vaccination types,

(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 national flu immunisation programme 2021 to 2022(**a**).

(4) P must have in place and keep under review at the pharmacy premises or any other premises or sites from which the service is to be provided appropriate standard operating procedures for the service (which may be available electronically), as described in direction

(**a**) See the letters published on gov.uk with PHE publications gateway number GW-1266 and 2020153.

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) P must ensure that the requirements in the service specification that apply to any responsible pharmacist and the superintendent pharmacist of P are adhered to, including through an appropriate governance framework.

(6) Vaccinations must be administered under the supervision of a pharmacist trained in vaccination (including having a clear understanding of this service), and a record must be maintained of who that person is at each premises at any given time while the service is being provided.

(7) Vaccines must only be administered by a registered pharmacist or pharmacy technician or, to the extent that the National Protocol or the National PGD and the CPSIVAS service specification permit, any authorised person, and—

(a) that registered pharmacist or pharmacy technician, or authorised person, must have completed the training required of that registered pharmacist, pharmacy technician or authorised person—them under the National PGD and the National Protocol, and must be competent to do so, having regard to the requirements of the National PGD, the National Protocol and the CPSIVAS service specification (including the relevant requirements of the National Minimum Standards(**a**) referred to in paragraph 4.5 of that specification), and to any JCVI guidance on the required interval between, or the co-administration of, vaccinations under this service and other vaccination types; and

(b) P must ensure that the training mentioned in sub-paragraph (a) must have been updated each year by any registered pharmacist, pharmacy technician or authorised person that P has employed or engaged to administer vaccines from the date the training was originally undertaken by that registered pharmacist, pharmacy technician or authorised person, and in addition, P must ensure that face to face training for injection technique and basic life support (including administration of adrenaline for anaphylaxis) must have been undertaken by any such registered pharmacist, pharmacy technician or authorised person every three years from the time they last undertook such training;

(c) that registered pharmacist or pharmacy technician, or authorised person, must be authorised by name under the National PGD or the National Protocol before working to it; and

(d) that registered pharmacist or pharmacy technician, or authorised person, must adhere to—

(i) the National PGD or a National Protocol,

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

(iii) 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(7).

(7) In respect of each occasion on which P intends to administer vaccines at a site other than the pharmacy premises as part of the CPSIVAS—

(a) P must ensure that appropriate arrangements are in place at the care home or the patient's home, or any other location at which the service is being provided, (having regard to the standard operating procedures mentioned in direction 7A(6))

(**a**) These are available at https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners.

(**b**) Available at www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book.

for the handling, removal and safe disposal of any clinical waste related to the provision of the service;

(b) where vaccinations are administered at—

(i) a care home, P must ensure that vaccinations are only administered in a room or any other location which P considers suitable having regard to the standard operating conditions mentioned in paragraph (4),

(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), or

(iii) any other acceptable location within the meaning of direction 7A(7), P must ensure that vaccinations are only administered in a location which P considers suitable having regard to the standard operating procedures mentioned in paragraph (4) and the professional standards required by the General Pharmaceutical Council and the CPSIVAS service specifications; and

(c) P must ensure that appropriate infection control is available at the care home, the patient's home, or any other location at which the service is provided.

(8) 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**)).

(9) 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 or the National Protocol).

(10) P must ensure the patient's verbal consent to the administration of the vaccine is obtained and recorded on the pharmacy's clinical record for the service, and this information must be shared on request with the NHSCB, where it is needed for assurance and post payment verification.

(11) 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 in accordance with the CPSIVAS service specification, in the manner provided for in that service specification.

(12) If —

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

(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, the National Protocol and the CPSIVAS service specification.

(13) 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, the National Protocol 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

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

(b) for the purposes specified in the National PGD, the National Protocol and the CPSIVAS service specification, and to ensure compliance with any JCVI guidance on the required interval between, or the co-administration of, vaccinations under this service and other vaccination types:

(14) NHSCB must terminate any arrangements that are entered into or still in force on 31st March 2022 with effect from the end of 31st March 2022.".

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

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

1st September 2021