THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (Amendments Relating to the Adult Influenza Vaccination Service) (England) Directions 2025

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) (Amendments Relating to the Adult Influenza Vaccination Service) (England) Directions 2025.

(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**).

(**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 by the Health and Care Act 2022 (c. 31) ("the 2022 Act") Schedule 1, paragraph 1. Section 128 has been amended by the 2012 Act, Schedule 4, paragraph 65, and by the 2022 Act, Schedule 1, paragraph 1.

(**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; 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) (Further Amendments) Directions 2022, signed on 24th August 2022; the

Amendment of direction 2 of the 2013 Direction

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

(2) For the definition of "CPSIVAS service specification"(**a**) substitute—

""CPSIVAS service specification" means the service specification for the community pharmacy seasonal influenza vaccination advanced service entitled "Community pharmacy advanced service specification Seasonal influenza vaccination 1 September 2025 - 31 March 2026", or that service specification, if it is revised by NHS England, as revised by NHS England from time to time;"(**b**).

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

""National PGD" means the patient group direction entitled "Inactivated influenza vaccine (IIV) Patient Group Direction (PGD) authorised by NHS England, or that patient group direction, if it is revised by the UK Health Security Agency (UKHSA), as revised by UKHSA from time to time;"(**d**).

(4) For the definition of "the National Protocol"(**e**) substitute—

""National Protocol" means the protocol entitled "National protocol for inactivated influenza vaccine (IIV)" authorised by Department of Health and Social Care Ministers pursuant to regulation 247A of the Human Medicines Regulations 2012(**f**), or that protocol, if it is revised by Department of Health and Social Care Ministers, as revised by them from time to time;"(**g**).

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

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

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

7A.—(1) NHS England 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 (10); and

Pharmaceutical Services (Advanced and Enhanced Services) (Amendment) (England) Directions 2023, signed on 28th March 2023; the Pharmaceutical Services (NHS Pharmacy Contraception Service and Other Amendments) (England) Directions 2023, signed on 17th April 2023; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Further Amendments) Directions 2023, signed on 29 August 2023; the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (No. 2) (England) Directions 2023, signed on 3rd November 2023; the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (No. 3) (England) Directions 2023, signed on 30th November 2023; the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (No. 4) (England) Directions 2023, signed on 19th December 2023; and the Pharmaceutical Services (Advanced and Enhanced Services) (Amendments Relating to Influenza Vaccination Service) (England) Directions 2024, signed on 29th August 2024.

(**a**) Inserted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2019, signed on 22nd August 2019, and amended each subsequent year prior to this year to update the date of the publication of the revised service specification.

(**b**) NHS publication approval reference: PRN01998_v

(**c**) As substituted by the Pharmaceutical Services (Advanced and Enhanced Services) (Amendments Relating to the Influenza Vaccination Service) (England) Directions 2024, signed on 29th August 2024.

(**d**) UKHSA publications gateway number: GOV-18488.

(**e**) As substituted by the Pharmaceutical Services (Advanced and Enhanced Services) (Amendments Relating to the Influenza Vaccination Service) (England) Directions 2024, signed on 29th August 2024.

(**f**) Inserted by S.I. 2020/1125 and amended by S.I. 2021/1452 and 2024/344.

(**g**) UK Health Security Agency publication gateway number: GOV-18486.

(**h**) As substituted by the Pharmaceutical Services (Advanced and Enhanced Services) (Amendments Relating to the Influenza Vaccination Service) (England) Directions 2024, signed on 29th August 2024.

(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 and the National Protocol—

(a) to sustain and maximise uptake of seasonal influenza vaccination in at risk groups;

(b) to protect those who are most at risk of serious illness or death should they develop seasonal influenza; and

(c) to provide more opportunities and improve convenience for eligible patients to access seasonal influenza vaccinations.

(3) P must be satisfactorily complying with P's obligations under Schedule 4 to the Pharmaceutical Services Regulations (Terms of service of NHS pharmacies) in respect of the provision of essential services and an acceptable system of clinical governance.

(4) Any vaccinator 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, having undertaken appropriate training in line with the National Minimum Standards and Core Curriculum for Immunisation Training, and annual updates must be undertaken to ensure knowledge and practice remain current (competence can be demonstrated by using, for example, the vaccination services Declaration of Competence(**a**) for registered pharmacy professionals or the UKHSA competency assessment tool(**b**)).

(5) Any vaccinator who is to be providing the service at a patient's own home (including a care home) must have a valid Disclosure and Barring Service (DBS) certificate.

(6) Pharmacy staff who are not vaccinators, and 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, including updates, having regard to requirements of the National PGD, the National Protocol and the CPSIVAS service specification.

(7) The responsible pharmacist at the pharmacy premises at or from which the service is to be provided, is professionally responsible for overseeing this advanced service, and if the responsible pharmacist is unable to provide sufficient oversight, for example due to workload or where vaccinations are undertaken off the pharmacy premises, an on-site pharmacist or pharmacy technician responsible for the delivery of the advanced service must be linked and work closely with the responsible pharmacist and the superintendent pharmacist through an appropriate governance framework to ensure appropriate oversight of the service.

(8) P must have in place, at the pharmacy premises or for any other locations 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, about which pharmacy 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 and cold chain storage;

(b) needle stick injuries;

(**a**) The Declaration of Competence is available on the CPPE website: https://www.cppe.ac.uk/doc
(**b**) Available at https://www.gov.uk/government/publications/flu-immunisation-training-recommendations

(c) the identification and management of adverse reactions;

(d) the handling, removal and safe disposal of any clinical waste and personal protective equipment relating to the provision of the service; and

(e) providing the service away from the pharmacy premises.

(9) 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, where the service is being provided—

(a) at P's pharmacy premises—

(i) in a room for consultations which meets the applicable requirements of paragraph 28A of Schedule 4 to the Pharmaceutical Services Regulations(**a**) (premises requirements in respect of consultation rooms), or

(ii) at an alternative location where there are suitable facilities available (allowing for infection control standards to be maintained and patient confidentiality and dignity to be respected), but only to the extent this is permitted by the CPSIVAS service specification;

(b) elsewhere other than P's pharmacy premises, including at a patient's home or community venue, a location where there are suitable facilities available (allowing for infection control standards to be maintained and patient confidentiality and dignity to be respected), but only to the extent that this is permitted by the CPSIVAS service specification, and P must obtain consent from the commissioner if they wish to carry out vaccinations at a location other than at P's pharmacy premises.

(10) P must ensure that where vaccinations are undertaken off the pharmacy premises, P has in place arrangements to ensure there is an on-site pharmacist or pharmacy technician responsible for the delivery of the advanced service (or delivering the influenza vaccination service themselves) and that vaccinators—

(a) are delivering vaccines in accordance with the National PGD or the National protocol, as appropriate;

(b) have professional indemnity that covers off-site vaccinations;

(c) continue to adhere to all professional standards relating to vaccinations;

(d) follow appropriate cold-chain storage measures;

(e) ensure that the setting used to administer the vaccination is appropriate (allowing for patient confidentiality to be respected); and

(f) appropriately dispose of any clinical waste or personal protective equipment used during the vaccination process.

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

7B.—(1) NHS England 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) Only inactivated influenza vaccines are to be administered as part of the service, and they must be administered in accordance with the requirements of the National PGD or the National Protocol (that is, all the requirements of the National PGD or the National Protocol, whether they are to apply before, during or after administration of a vaccine).

(**a**) Inserted by S.I. 2020/1126 and amended by S.I. 2023/1071.

(3) The only inactivated influenza vaccines to be administered as part of the service are those permitted by or by virtue of the CPSIVAS service specification.

(4) Vaccines must only be administered to eligible patients, as determined in accordance with the eligibility criteria provided by or by virtue of the CPSIVAS service specification (which include criteria as to when particular patient cohorts may be vaccinated, and when the service as a whole is to start and finish).

(5) P must have in place and keep under review at the pharmacy premises or any other locations from which the service is to be provided appropriate standard operating procedures for the service (which may be available electronically), as described in direction 7A(8), about which pharmacy staff (if there is any role that they may be asked to perform as part of the service) must have received appropriate training.

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

(7) The responsible pharmacist at the registered pharmacy premises is professionally responsible for overseeing this advanced service, and if the responsible pharmacist is unable to provide sufficient oversight, for example due to workload or where vaccinations are undertaken off the pharmacy premises, an on-site pharmacist or pharmacy technician responsible for the delivery of the advanced service must be linked and work closely with the responsible pharmacist and superintendent pharmacist through an appropriate governance framework to ensure appropriate oversight of the service.

(8) Vaccines must only be administered by an appropriately trained vaccinator, and—

(a) P must ensure that every vaccinator must have completed the training, including any updates. required of that person under the National PGD, the National Protocol and the CPSIVAS service specification, and must be competent to perform the tasks required of them, having regard to the applicable requirements of the National PGD, the National Protocol and the CPSIVAS service specification;

(b) every vaccinator must be authorised by name to administer vaccines under the National PGD or the National Protocol before working to it;

(c) P must ensure that every vaccinator who provides the service at a patient's own home (including a care home) has a valid Disclosure and Barring Service (DBS) certificate; and

(d) any person involved in the administration of the vaccine must adhere to—

(i) the National PGD or the National Protocol, whichever is appropriate,

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

(iii) as appropriate, the standard operating procedures referred to in paragraph (5).

(9) P must only provide the service at an acceptable location, and for these purposes, "acceptable location" has the same meaning as in direction 7A(9).

(10) If the service is provided at P's pharmacy premises and the patient expresses a preference for the vaccination to take place in a consultation room, P must respect that preference.

(11) Where the service is provided elsewhere than at P's pharmacy premises, P must ensure that all P's vaccinators are covered by an insurance or indemnity arrangement that

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

covers vaccinating at the premises where the service is provided, and P must also ensure that, on each occasion the service is provided elsewhere than at P's premises, what needs to be in place by virtue of direction 7A(10) is also adhered to.

(12) P must not refuse to provide the service to a patient in the event that they are not registered with a general practitioner in England or because they do not have a NHS number.

(13) 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 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 eligibility requirements of the National PGD, the National Protocol and the CPSIVAS service specification).

(14) Prior to vaccinations, P must—

(a) seek and record the consent of the patient to the administration of the vaccine;

(b) provide the patient with the patient information leaflet for the vaccine or direct them to a version of the leaflet on a website; and

(c) as appropriate, advise them about the handling of information about them relating to the provision of the service, to the extent that this is provided for, and in the manner in which this is provided for, in the National PGD, the National Protocol and the CPSIVAS service specification, and which includes advising the patient about—

(i) the sharing of information with their general practitioner (if they have one), and

(ii) how their information may be pseudonymised and used by NHS England for the purposes of service delivery, evaluation and research.

(15) As regards each patient vaccinated as part of the service who is registered with a general practitioner, P must ensure that the patient's general practitioner is notified (where this is known) in accordance with the CPSIVAS service specification, including in the manner provided for in the CPSIVAS service specification.

(16) If—

(a) a patient vaccinated as part of the service 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, and in the manner provided for in the National PGD, the National Protocol and the CPSIVAS service specification.

(17) P must ensure that any patient safety incidents relating to the provision of the service are reported in line with the clinical governance approved particulars for pharmacies published by NHS England(**a**), and if those particulars are revised by NHS England, as revised by NHS England from time to time.

(18) P must maintain appropriate electronic records of P's provision of the service, in accordance with the CPSIVAS service specification, including—

(**a**) Available at www.england.nhs.uk/publication/approved-particulars/.

(a) using a NHS assured point of care system in the manner required by, and for the purpose specified in, the National PGD, the National Protocol and the CPSIVAS service specification;

(b) having robust user and access management processes (with frequent updates to system access levels); and

(c) ensuring same day record keeping (unless exceptional circumstances beyond P's control apply).

(19) P must comply with the arrangements for sharing data with NHS BSA and the service commissioners that are necessary for the performance of obligations under the National PGD, the National Protocol and the CPSIVAS service specification that are part of the management of the service, with any sharing of personal data being subject to an appropriate level of confidentiality.

(20) If P temporarily or permanently ceases to provide the service, P must update their NHS website profile as soon as possible to reflect the fact that the service is not available at P's pharmacy (or elsewhere from P)."

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

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

28 August 2025