THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (Amendments Relating to the Childhood 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 Childhood 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 Directions

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

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

""Commissioner" means the organisation with responsibility for contract managing these advanced service arrangements (and for the time being this is NHS England);";

""CPCSIVAS service specification" means the service specification for the community pharmacy childhood seasonal influenza vaccination advanced service entitled "Community pharmacy advanced service specification Childhood seasonal influenza vaccination 1 October 2025 - 31 March 2026", or that service specification, if it is revised by NHS England, as revised by NHS England from time to time(**a**);";

""CPIV PGD" means the Patient Group Direction entitled "Community Pharmacy Influenza Vaccine (2 and 3 years of age)" 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(**b**);";

""FDP" means the Federated Data Platform, which is the national data platform managed by NHS England and which hosts the vaccine supply and ordering tools that NHS England operates (pharmacy contractors must register for the FDP to manage their vaccine orders and submit stock takes for this service);";

""NBS" means the National Booking System, the national system used by patients to book vaccination appointments;";

""Service Commencement Date" means the date from which the administration of influenza vaccinations to children aged two and three years old shall commence and which shall be following an announcement by the Commissioner. (The Service Commencement Date in community pharmacy is 1 October 2025 for children aged two and three years old unless otherwise announced by the Commissioner.);".

New directions 7BA and 7BB of the 2013 Directions

3. After direction 7B of the 2013 Directions (Community Pharmacy Seasonal Influenza Advanced Service: ongoing conditions of arrangements), insert—

"Community Pharmacy Childhood Seasonal Influenza Vaccination advanced service: general matters and preconditions to making arrangements

7BA.—(1) NHS England must make arrangements for the provision of a service as part of the CPCSIVAS with any pharmacy contractor (P) who—

(a) meets the requirements set out in paragraphs (2) to (21); and

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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**) NHS publication approval reference: PRN02049.

(**b**) NHS Publication Approval Reference: PRN02117

(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 CPCSIVAS is to enable P to participate in arrangements for the administration of live attenuated influenza vaccine (LAIV) nasal spray suspension and inactivated influenza vaccine to patients in accordance with the CPIV PGD—

(a) to sustain and maximise uptake of seasonal influenza vaccination in children aged two and three years old;

(b) to protect those children against strains of the influenza virus and reduce the transmission of influenza in the wider population, some of whom are most at risk of serious illness or death should they develop seasonal influenza; and

(c) to provide more opportunities and improve convenience for children aged two and three years old 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) P must be providing at least one NHS commissioned vaccination service and one service that involves the assessment or treatment of children (for example the NHS Pharmacy First Service).

(5) P must notify NHS England that they intend to provide the Childhood Seasonal Influenza Vaccination Service by completion of an electronic registration declaration through the NHS BSA MYS portal.

(6) P must register on MYS by 23:59 on 31 August 2025 to receive vaccine ahead of the Service Commencement Date. P can register after this date and before the registration deadline, however it is not guaranteed they will receive vaccine in time for the Service Commencement Date. The deadline to register on MYS is 23:59 on 30 November 2025. If P do not register by this date, they will not be able to deliver the service in 2025/26.

(7) 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 CPIV PGD, the CPCSIVAS service specification, having undertaken appropriate training in line with the National Minimum Standards and Core Curriculum for Immunisation Training, as well as training to ensure they are competent to administer vaccines to children aged two and three years old using both the LAIV and inactivated flu vaccines, which could include the completion of the e-learning for health flu immunisation training for LAIV(**a**). (Competence can be demonstrated by using, for example, the vaccination services Declaration of Competence(**b**) for registered pharmacy professionals or the UKHSA competency assessment tool(**c**).)

(8) Any vaccinator who is to be providing the service must have a valid enhanced Disclosure and Barring Service (DBS) certificate for the adult and children's barred list.

(9) 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 CPIV PGD and the CPCSIVAS service specification.

(10) The responsible pharmacist at the registered pharmacy premises is professionally responsible for overseeing this advanced service, and if the responsible pharmacist is unable

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

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.

(11) 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 CPIV PGD and the CPCSIVAS 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;

(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.

(12) P must be able to provide the services which are part of the CPCSIVAS 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 CPCSIVAS 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 CPCSIVAS service specification. P must obtain consent from the commissioner if they wish to carry out vaccinations at a location other than at P's pharmacy premises.

(13) 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 CPIV PGD;

(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

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

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

(14) P must offer seasonal influenza vaccines through the NBS to patients, and must have arrangements in place to ensure compliance with the requirements of using the NBS, including ensuring that—

(a) accurate information is published and appointment or clinic times are uploaded in a timely way to allow patient bookings to take place;

(b) at least 20 appointments are listed in the first month after the Service Commencement Date;

(c) at least 10 appointments are listed per month after the first month, as defined in paragraph 18(b), to demonstrate continued service provision; and

(d) that appointments are available at various times throughout the pharmacy's full opening hours, including late afternoons and Saturdays (where the contractor is open on Saturdays).

(15) P must offer vaccinations through advertised walk-in clinics via the Pharmacy Services Finder, and must have arrangements in place to ensure the walk-in clinic times offered promote access to the service, including late afternoons and Saturdays (where the contractor is open on Saturdays).

(16) P must register for FDP to be able to order vaccines, and the LAIV must be ordered via FDP (the LAIV for all patients is centrally supplied as a nasal spray for children, unless contraindicated, and the vaccine is supplied free of charge and will not be reimbursed as part of the NHS Influenza Programme).

(17) P must have arrangements in place to ensure that all orders of LAIV are in line with national ordering restrictions. P will be able to order a minimum quantity of 10 doses (1 pack) of centrally supplied LAIV from the FDP. Participating P who register by 31 August 2025 will receive vaccine supply by the Service Commencement Date.

(18) P may only request subsequent supply of LAIV when—

(a) the pharmacy has recorded administration of at least 50% of the previously supplied doses; and

(b) current stock levels are confirmed to be below one pack; and

(c) appointments listed on NBS comply with the CPCSIVAS; or

(d) NBS booked appointments indicate a need for additional supply.

Any order that does not meet these requirements will be deferred until P evidences they have been met.

(19) P must plan clinics using the recommended first line vaccine for this cohort, which is LAIV. If P does not have stock of LAIV when a patient presents, they should be directed to an alternative provider who has stock of LAIV or told to rebook when the new stock is available.

(20) When LAIV is contraindicated, the recommended inactivated influenza vaccine must be used, as set out in Annex A to the CPCSIVAS (for which P will be reimbursed for in accordance with Part VIC of the Drug Tariff) and if P does not have the recommended inactivated influenza vaccine in stock, patients must be directed to an alternative provider who has stock of a recommended inactivated influenza vaccine or told to rebook when the new stock is available (under the CPCSIVAS, the recommended third line vaccine in the Flu Letter cannot be administered).

(21) P must have arrangements in place to ensure that the correct number of doses of vaccine are administered. Where two doses of vaccine are required, a failure to give both

doses may leave a child incompletely protected. Conversely, where only one dose of vaccine is indicated, payment will not be made for any second doses that are inadvertently given. Patients who are in clinical risk groups and who have not received influenza vaccination previously, will require a second dose of the appropriate vaccine at least four weeks after the first dose.

Community Pharmacy Childhood Seasonal Influenza Vaccination advanced service: ongoing conditions of arrangements

7BB.—(1) NHS England must ensure that arrangements pursuant to direction 7BA(1) with a pharmacy contractor (P) include terms equivalent to the requirements set out in this direction.

(2) LAIV and inactivated influenza vaccines are to be administered as part of the service, and they must be administered in accordance with the requirements of the CPIV PGD (that is, all the requirements of the CPIV PGD, whether they are to apply before, during or after administration of a vaccine).

(3) The only LAIV and inactivated influenza vaccines to be administered as part of the service are those permitted by or by virtue of the CPCSIVAS 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 CPCSIVAS 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) Prior to vaccination, informed consent(**a**) must be sought from the parent or guardian of each patient to the administration of the vaccine. Informed consent should be recorded in the pharmacy's clinical record (including persons that have consented on the patient's behalf and that person's relationship to the patient must also be recorded).

(6) During the consultation, if there are concerns about a potential safeguarding issue, then appropriate action should be taken, where necessary, in line with local safeguarding processes.

(7) 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 7BA(11), 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.

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

(9) 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.

(10) 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 CPIV PGD and the CPCSIVAS

(**a**) Available at https://www.gov.uk/government/publications/consent-the-green-book-chapter-2

service specification, and must be competent to perform the tasks required of them, having regard to the applicable requirements of the National PGD and the CPCSIVAS service specification;

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

(c) P must ensure that every vaccinator who provides the service has a valid enhanced Disclosure and Barring Service (DBS) certificate for the adult and children's barred list.; and

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

(i) the CPIV PGD,

(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).

(11) P must only provide the service at an acceptable location, and for these purposes, "acceptable location" has the same meaning as in direction 7BA(12).

(12) 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.

(13) 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 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 7BA(13) is also adhered to.

(14) 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.

(15) 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 CPIV PGD and the CPCSIVAS service specification).

(16) Prior to vaccinations, P must—

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

(b) provide the parent or guardian of 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 CPIV PGD and the CPCSIVAS service specification, and which includes advising the patient about—

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

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

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

(17) The parent or guardian of the patient must be informed that information relating to their vaccination will be shared with—

(a) their registered general practice, for the appropriate recording of the vaccination in their medical record;

(b) the NHS BSA for the purpose of making payments to the pharmacy and post-payment verification;

(c) the commissioner and the UKHSA for managing and monitoring vaccination programmes. Data that has been psyeudonymised may be used for evaluation and research purposes.

(18) 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 CPCSIVAS service specification, including in the manner provided for in the CPCSIVAS service specification.

(19) 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 and the CPCSIVAS service specification.

(20) 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.

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

(a) using a NHS assured point of care system in the manner required by, and for the purpose specified in, the CPIV PGD and the CPCSIVAS 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).

(22) 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 CPIV PGD and the CPCSIVAS 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.

(23) Where, by virtue of direction 7BA or this direction, it is a condition of providing the service that specified arrangements or plans are in place, or there are ordering, offering, administration or redirection requirements in respect of vaccines used as part of the service,

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

P must when providing the service continue to have and must adhere to those arrangements and plans, and to those ordering, administration and redirection requirements (not just where doing so is specifically provided for in other paragraphs of this direction).

(24) If P wishes to permanently stop providing the service, they must notify the Commissioner that they are no longer going to provide the service via the MYS portal, giving 30 days' notice prior to cessation of the service (pharmacy contractors that de-register before the Service Commencement Date are not required to give 30 days' notice). P may be asked for a reason as to why they wish to stop providing the service. P must ensure they update NBS, Pharmacy Services Finder and their NHS website profile when they cease provision of the service.

(25) 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).

(26) If P de-registers from the service, they will be unable to re-register for a period of four months from the date of re-registration."

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

Alette Addison
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28 August 2025 Department of Health and Social Care