THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendments Relating to Meningococcal B Vaccinations etc.) Directions 2026

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) (England) (Amendments Relating to Meningococcal B Vaccinations etc.) Directions 2026.

(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—

""CPMBVAS" means the Community Pharmacy Meningococcal B Vaccination Advanced Service;";

""CPMBVAS service specification" means the service specification for the community pharmacy Meningococcal B vaccination advanced service entitled "Community pharmacy advanced service specification: Meningococcal B vaccination service from 20 July 2026 - 31 March 2027", or that service specification if it is revised by NHS England, as revised by NHS England from time to time(**a**);"; and

""Meningococcal B vaccination" means the vaccine given to prevent Meningococcal disease which occurs because of a systemic bacterial infection caused by Neisseria meningitidis with antigenically distinct capsular B group;".

New directions 7BQ and 7BR of the 2013 Directions

3. After direction 7BP of the 2013 Directions (NHS Pharmacy First Service: ongoing conditions of arrangements)(**b**), insert—

"Community Pharmacy Meningococcal B Vaccination Advanced Service: general matters and preconditions to making arrangements

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

(a) meets the requirements set out in paragraphs (3) to (12);

(b) agrees to participate in the CPMBVAS; and

(c) has notified the Commissioner of their intention to provide Meningococcal B vaccinations to patients, by the relevant dates, and in the manner as set out in the CPMBVAS service specification.

(2) The aims of the CPMBVAS are—

(a) to protect those who are most at risk of serious illness or death should they develop Meningococcal disease; and

(b) to maximise uptake of two doses of Meningococcal B vaccinations in the eligible population within specified timescales.

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; the Pharmaceutical Services (Advanced and Enhanced Services) (Amendments Relating to Influenza Vaccination Service) (England) Directions 2024, signed on 29th August 2024; the Pharmaceutical Services (Advanced and Enhanced Services) (Amendments Relating to the Adult Influenza Vaccination Service) (England) Directions 2025, signed on 28th August 2025; the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (England) Directions 2025, signed on 24th October 2025; and the Pharmaceutical Services (Advanced and Enhanced Services) (Amendments Relating to the COVID-19 and Adult Influenza Vaccination Service) (England) Directions 2026, signed on 26th March 2026.

(**a**) NHS publication approval reference: PRN0249.

(**b**) Inserted by the Pharmaceutical Services (Advanced and Enhanced Services) (Further Amendments) (No. 4) (England) Directions 2023, signed on 19th December 2023.

(3) P must be satisfactorily complying with P's obligations under Schedule 4 to the PLPS 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 (in addition to the CPMBVAS).

(5) P must be able to provide the services which are part of the CPMBVAS 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 PLPS 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 CPMBVAS service specification;

(b) elsewhere other than P's pharmacy premises, including a university campus or other community venue, 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—

(i) this is permitted by the CPMBVAS service specification, and

(ii) P has obtained consent from the Commissioner.

(6) P must have in place appropriate standard operating procedures for the service, having regard to the CPMBVAS 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;

(b) the escalation of any issues identified (clinical and non-clinical);

(c) signposting details;

(d) record keeping; and

(e) staff training.

(7) The responsible pharmacist at the registered pharmacy premises at or from which the service is to be provided is to be professionally responsible for overseeing the CPMBVAS, and if the responsible pharmacist is unable to provide sufficient oversight, (for example due to workload or where vaccinations are undertaken away from the pharmacy premises) the on-site pharmacist or pharmacy technician who is to be responsible for the delivery of the CPMBVAS 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 be familiar and comply with all guidance relating to the administration, handling and storage of the vaccine as required by the CPMBVAS service specification, and P must oversee and keep a record to confirm that all staff have undertaken the relevant training prior to participating in the service and that all staff remain competent in line with the specific skills and knowledge as required by the CPMBVAS service specification and

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

in line with professional standards throughout their participation in the service and are authorised to use the relevant legal mechanisms.

(9) P must ensure that all those involved in delivering vaccination activity as part of the CPMBVAS have an enhanced Disclosure and Barring Service (DBS) certificate demonstrating that they have been checked against the children's barred list.

(10) P must ensure that where vaccinations are undertaken away from 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 CPMBVAS off-site (or delivering the vaccination service themselves) and that—

(a) vaccines are administered by appropriately trained vaccinators in line with the appropriate legal mechanism;

(b) P (at a corporate level) has indemnity arrangements in place that cover off-site vaccination;

(c) staff continue to adhere to all professional standards relating to vaccination;

(d) staff follow appropriate cold chain storage measures;

(e) the setting used to administer the vaccines is appropriate (including ensuring patient confidentiality and dignity can be respected); and

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

(11) P must order the vaccine (which is to be centrally supplied) via the federated data platform(**a**), and P must adhere to the requirements in the CPMBVAS service specification and national ordering restrictions in relation to monitoring and the ordering of the vaccine, including in relation to ordering subsequent supply of the vaccine (and failure to report vaccine usage or stock levels accurately may result in temporary suspension of supply).

(12) P is to be responsible for the supply of consumables including suitable needles to be used with the pre-filled syringe of the vaccine.

Community Pharmacy Meningococcal B Vaccination Advanced Service: ongoing conditions of arrangements

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

(2) Only Meningococcal B vaccines are to be administered as part of the service, and the vaccine must be administered in accordance with requirements of the CPMBVAS service specification and the Green Book(**b**) (which outlines relevant details on the dosage, timings and administration of the Meningococcal B vaccine, as well as details on disposal of clinical waste) and within the dates published in the bipartite letter jointly issued by NHS England and UKHSA(**c**) and set out in the CPMBVAS service specification.

(3) The only Meningococcal B vaccines to be administered as part of the service are those permitted by or by virtue of the CPMBVAS service specification.

(4) Vaccines must only be administered to patients who are eligible to receive the vaccination in line with the CPMBVAS service specification, but any updates to the

(**a**) Available at https://www.england.nhs.uk/digitaltechnology/nhs-federated-data-platform/.
(**b**) The up-to-date version is available at https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book.
(**c**) The up-to-date version is available at https://www.gov.uk/government/publications/meningococcal-b-menb-time-limited-vaccination-offer-letter/meningococcal-b-menb-time-limited-vaccination-offer-letter.

eligibility criteria are to take effect from the date of the change announced by the Commissioner (which may be an earlier date than the date of the consequential updating of the CPMBVAS service specification).

(5) P must have in place and keep under review at the pharmacy premises or any other location from which the service is to be provided appropriate standard operating procedures for the service as described in direction 7BQ(6), 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, and P must ensure that the requirements of the CPMBVAS service specification that apply to any responsible pharmacist and the superintendent pharmacist of P are adhered to, including through an appropriate governance framework.

(6) The responsible pharmacist at the registered pharmacy premises at or from which the service is to be provided is to be professionally responsible for overseeing the CPMBVAS, and if the responsible pharmacist is unable to provide sufficient oversight, (for example due to workload or where vaccinations are undertaken away from the pharmacy premises) the on-site pharmacist or pharmacy technician who is to be responsible for the delivery of the CPMBVAS 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.

(7) Vaccines must only be administered by an appropriately trained vaccinator and P must ensure that those involved in vaccination activity—

(a) have the necessary experience and competence to administer vaccines in line with the requirements of the CPMBVAS service specification, and records of training must be kept in line with those requirements;

(b) have the necessary experience, skills and training with regard to the recognition and initial management of anaphylaxis;

(c) are competent to deliver the service having regard to the applicable requirements of the CPMBVAS service specification;

(d) understand and are authorised to work under the relevant valid legal mechanism for administration of the vaccine;

(e) have read and understood the clinical guidance published in the bipartite letter (jointly issued by NHS England and UKHSA) and associated information for healthcare practitioners, and have a process in place to check any updates to those documents and the relevant valid legal mechanisms;

(f) are appropriately trained and made aware of the risks associated with the handling and disposal of clinical waste and that correct procedures are used to minimise those risks, including a needle stick injury procedure;

(g) have a valid enhanced DBS check against the children's barred list; and

(h) have the knowledge to recognise the signs and symptoms of meningitis and sepsis and are able to communicate these to patients.

(8) In relation to vaccine supply, handling and storage, P must ensure that—

(a) the receipt, storage, transportation and preparation of all vaccines is in accordance with any relevant medicines legislation, manufacturer's, Medicines and Healthcare products Regulatory Agency (MHRA), UKHSA and NHS England's instructions, and all associated guidance in the Green Book and is undertaken with appropriate cold chain management (including appropriate and timely action when temperature deviations occur), clinical oversight and in accordance with governance arrangements which are in place in line with the CPMBVAS service specification;

(b) robust and reliable stock management processes are in place to minimise vaccine wastage while ensuring sufficient vaccine is available to support the vaccination offer to patients, and to mitigate risks associated with handling multiple vaccine types; and

(c) the vaccine is only stored overnight at General Pharmaceutical Council registered premises or locations that are conditions of Care Quality Commission registration and in accordance with medicines management arrangements that have been approved by the Commissioner.

(9) P must only provide the service at an acceptable location, and for those purposes, "acceptable location" has the same meaning as in direction 7BQ(5), and where the patient expresses a preference for a vaccination to take place in a consultation room, P must respect that preference.

(10) Where the service is provided elsewhere than at P's pharmacy premises, P must ensure that all P's vaccinators are covered by an 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 7BQ(10) is also adhered to.

(11) P must ensure the service is accessible, appropriate and sensitive to the needs of all service users (and P is encouraged to put in place processes to support patients with communication needs and encourage vaccination of patients who experience other difficulties in accessing healthcare), and that no patient is excluded or experiences particular difficulty in accessing and effectively using this service due to a protected characteristic, as outlined in the Equality Act 2010, including age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation.

(12) Prior to the vaccine being administered—

(a) the patient must be assessed as eligible to receive the service in accordance with the CPMBVAS service specification; and

(b) the patient's informed consent to the administration of the vaccine must be obtained and recorded in the pharmacy's clinical record.

(13) As regards information sharing, P must ensure that the patient is informed that information relating to the vaccination will be shared with—

(a) the patient's registered general practice for the appropriate recording of the vaccination in the medical record;

(b) NHS BSA for the purpose of payments and post payment verification; and

(c) the Commissioner and the UKHSA for managing and monitoring the vaccination programme (and data that has been pseudonymised may be used for evaluation and research purposes).

(14) During the appointment for the first dose of the Meningococcal B vaccination—

(a) the patient must be informed that for protection it is recommended that a second dose must be administered at least 28 days after the first dose (and the patient should be encouraged to make an appointment for the second dose);

(b) the patient must be informed that the second dose does not have to be administered at the same community pharmacy as their first dose; and

(c) the patient must be advised of the signs and symptoms of meningitis and sepsis.

(15) If—

(a) a patient presents with an adverse drug reaction following the initial vaccination; and

(b) a pharmacist who is P or who is employed or engaged by P believes the adverse reaction is of clinical significance such that the patient's registered general practice should be informed,

this information should be shared with the registered general practice as soon as possible and a report submitted to the MHRA under the Yellow Card Scheme(**a**), and P must report any patient safety incidents in line with the Clinical Governance Approved Particulars for pharmacies, and follow the UKHSA: "Vaccine incident guidance"(**b**) and local NHS arrangements for responding to and reporting errors in vaccine storage, handling and administration.

(16) P must offer Meningococcal B vaccinations to patients through the national booking service(**c**) and through advertised walk-in clinics via the pharmacy services finder(**d**), and must comply with the requirements and minimum publication standards for national booking as set out in the CPMBVAS service specification (including that at least 100 appointments be listed per month from the service commencement date and that appointments are available at various times throughout the pharmacy's full opening hours), and 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 an NHS number.

(17) P must maintain appropriate and accurate electronic records to ensure effective ongoing service delivery in line with the terms of the CPMBVAS service specification.

(18) If P temporarily ceases to provide the service, P must do so in the manner provided for in the CPMBVAS service specification, and where possible, P must also alert the Commissioner before P temporarily ceases to provide the service to allow the Commissioner time to ascertain whether the temporary cessation of the service could be prevented.

(19) If P wishes to permanently cease to provide the service, P must do so in the manner provided for in the CPMBVAS service specification, including that P must continue to provide the service for the duration of the notice period, and the conditions relating to de-registration set out in the CPMBVAS service specification are to apply.".

Amendments to direction 14 of the 2013 Directions

4. In direction 14(1) of the 2013 Directions (enhanced services provided by pharmacy contractors)—

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

(b) at the end of sub-paragraph (u), for "satisfied.", substitute "satisfied; and"; and

(c) after sub-paragraph (u), insert the following sub-paragraph—

"(v) a Vaccine Group Direction Service, the underlying purpose of which is for P to supply or administer vaccines to patients under vaccine group directions.".

(**a**) Available at https://yellowcard.mhra.gov.uk/.
(**b**) The up-to-date version is available at https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors.
(**c**) Available at https://digital.nhs.uk/services/vaccinations-national-booking-service.
(**d**) Available at https://www.nhs.uk/service-search/pharmacy/.

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

Peter Lilford
Deputy Director, Pharmacy, Eye Care and Controlled Drugs
Department of Health and Social Care

16th July 2026