THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Further Amendments) Directions 2023

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) (Further Amendments) Directions 2023.

(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. Section 273 has been amended by the 2012 Act, Schedule 4, paragraph 137, 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 Pharmaceutical Services (Advanced and Enhanced Services) (Amendment) (England) Directions 2023, signed on 28th March 2023; and the Pharmaceutical Services (NHS Pharmacy Contraception Service and Other Amendments) (England) Directions 2023, signed on 17th April 2023.

Amendment of direction 2 of the 2013 Directions

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

(2) In the definition of "CPSIVAS service specification", for "August 2022" substitute "August 2023".

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

""National PGD" means the Patient Group Direction authorised by NHS England in respect of the administration of inactivated influenza vaccine in accordance with the CPSIVAS and the national flu immunisation programme 2023/24, which is valid from 1st September 2023 and has the published expiry date of 31st March 2024(**b**) (and which may be revised from time to time);".

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

""the National Protocol" means the protocol under regulation 247A of the Human Medicines Regulations 2012(**d**) (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 2023/24, which is valid from 1st September 2023(**e**) (and which may be revised from time to time);".

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

3. For directions 7A and 7B of the 2013 Directions(**f**) (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 2024, 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 (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 NHS England's, the UK Health Security Agency's and the Department of Health and Social Care's national flu immunisation programme 2023 to 2024(**g**).

(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

(**a**) As substituted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Further Amendments) Directions 2022, signed on 24th August 2022.
(**b**) This is available at: https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service.
(**c**) Inserted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Further Amendments) Directions 2022, signed on 24th August 2022.
(**d**) S.I. 2012/1916; regulation 247A was inserted by S.I. 2020/1125.
(**e**) This is available at https://www.gov.uk/governent/publications/national-protocol-for-inactivated-influenza-vaccine.
(**f**) As substituted by the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Further Amendments) Directions 2022, signed on 24th August 2022.
(**g**) See the joint letter that was published on 3rd July 2023 and which is available at: https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan/national-flu-immunisation-programme-2023-to-2024-letter.

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(**a**) (including the relevant requirements of the National Minimum Standards(**b**)referred to in paragraph 4.5 of that specification).

(5) Other 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, including updates, having regard to requirements of the National PGD, the National Protocol and the CPSIVAS service specification.

(6) 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 staff (if there is any role that they may be asked to perform as part of the service) have received appropriate training and which include procedures in respect of—

(a) cold chain integrity;

(b) needle stick injuries;

(c) the identification and management of adverse reactions;

(d) 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

(e) 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) where the service is being provided at P's pharmacy premises—

(i) a room for consultations at P's pharmacy premises which meets the applicable requirements of paragraph 28A of Schedule 4 to the Pharmaceutical Services Regulations, or

(ii) other locations at P's pharmacy premises where suitable facilities are available, infection control standards can be maintained and patient confidentiality and dignity respected;

(b) where the service is being provided at a premises or site other than P's pharmacy premises or the patient's home, a location—

(i) 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 meets the standards for such locations required by the General Pharmaceutical Council, and

(ii) where suitable facilities are available, infection control standards can be maintained and patient confidentiality and dignity respected; or

(c) 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).

(**a**) This is available at: https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service.
(**b**) These are available at https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners.

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) 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.

(3) The only inactivated influenza vaccines to be administered under the arrangements must be those listed in NHS England's, the UK Health Security Agency's and the Department of Health and Social Care's national flu immunisation programme 2023 to 2024 joint letter(**a**).

(4) 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(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 CPSIVAS service specification(**b**) 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 an appropriate 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, to the extent that the National Protocol and the CPSIVAS service specification permit, another appropriately trained vaccinator, and—

(a) P must ensure that every person involved in the administration of the vaccine must have completed the training, including any updates, required of that person under the National PGD or the National Protocol, 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 (including the relevant requirements of the National Minimum Standards(**c**) referred to in paragraph 4.5 of that specification);

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

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

(i) the National PGD or the National Protocol,

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

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

(8) 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).

(**a**) See the joint letter that was updated on 3rd July 2023 and which is available at: https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan/national-flu-immunisation-programme-2023-to-2024-letter.

(**b**) This is available at: https://www.england.nhs.uk/publication/community-pharmacy-seasonal-influenza-vaccine-service.

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

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

(9) 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.

(10) P must ensure the service is accessible, appropriate and sensitive to the needs of all service users, and that no eligible patient is excluded or experiences particular difficulty in accessing or using the service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age (subject to the requirements of the National PGD or the National Protocol).

(11) Prior to vaccination, P must—

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

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

including advising the patient about how that information may be pseudonymised and used by NHS England for the purposes of service delivery, evaluation and research.

(12) 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 (where this is known) in accordance with the CPSIVAS service specification, in the manner provided for in that service specification.

(13) 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.

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

(a) using a NHS assured point of care system 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 vaccinator and, in the case of electronic records, password protection; and

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

(15) NHS England must terminate any arrangements that are entered into or still in force on 31st March 2024 with effect from the end of 31st March 2024.".

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

Edward Scully
Director of Primary and Community Health Care
Department of Health and Social Care

29 August 2023