Community Pharmacy Seasonal Influenza Vaccination Advanced Service

The Amendments to The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 have been finalised by the Department of Health providing the legal basis for the provision of the new Advanced Service 'Community Pharmacy Seasonal Influenza Vaccination Advanced Service' which came into force on 16th September 2015. The Directions will be published in the October Drug Tariff and are reproduced below with the amendment to Part VIC of the September Drug Tariff, detailing how the payment will be made.

Amendment to Part VIC of the Drug Tariff

National Influenza Adult Vaccination Service

15. A fee of £7.64 will be paid for each adult flu vaccination administered by a pharmacy contractor. An additional fee of £1.50 will be paid to cover training and clinical waste costs associated with the vaccination.

16. Pharmacy contractors will be reimbursed the cost of the vaccine in accordance with Part II, Clause 8C (Basic Price) of the Drug Tariff. An allowance at the applicable VAT rate will also be paid.

17. The fees will be payable only to contractors meeting the requirements of the service. These are set out in directions 7A and 7B of the principle Directions and the service specification.

18. Payments will be made monthly, via NHS Prescription Services on receipt of the Community Pharmacy Seasonal Influenza Vaccination claim form. The form must be sent with the FP34C reimbursement and remuneration claim form and received no later than the 5th day of the month following that in which the vaccination was administered.

THE NATIONAL HEALTH SERVICE ACT 2006

The Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2015

The Secretary of State gives the following Directions in exercise of the powers conferred by sections 127, 128, 272(7) and (8) and 273(1) of the National Health Service Act 2006(**a**).

Citation, commencement, application and interpretation

1.—(1) These Directions may be cited as the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2015.

(2) These Directions come into force on the day after the day on which they are signed.

(3) These Directions apply in relation to England.

(4) In these Directions, "the 2013 Directions" means the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013(**b**).

Amendment of direction 2 of the 2013 Directions

2. In direction 2 of the 2013 Directions (interpretation), insert each of the following definitions at the appropriate place in the alphabetical order—

> ""care home" means a care home within the meaning of the Care Standards Act 2000(**c**) in respect of which an organisation is registered under Chapter 2 of Part 1 of the Health and Social Care Act 2008(**d**) (the Care Quality Commission – registration in respect of the provision of health or social care) in respect of a regulated activity (within the meaning of that Part) carried on in the home;";
>
> "National PGD" means the Patient Group Direction developed by Public Health England in respect of the administration of intramuscular inactivated influenza vaccine for the national immunisation programme for active immunisation against influenza, which has the published expiry date of 31st August 2016(**e**) (and which may be revised by Public Health England from time to time);";
>
> "NIAVS" means the National Influenza Adult Vaccination Service, described in direction 7A(2);";

(**a**) 2006 c. 41. Section 127 has been amended by the Health and Social Care Act 2012 (c. 7) ("the 2012 Act"), Schedule 4, paragraph 64; and section 128 has been amended by the 2012 Act, Schedule 4, paragraph 65.

(**b**) Signed on 12th March 2013, and amended by: the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2013, signed on 16th September 2013; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2013, signed on 6th December 2013, which also revoked the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2013; the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) Directions 2014, signed on 12th March 2014; and the Pharmaceutical Services (Advanced and Enhanced Services) (England) (Amendment) (No. 2) Directions 2014, signed on 5th December 2014.

(**c**) 2000 c. 14. *See* section 3 of that Act, which defines what a care home is for the purposes of that Act.

(**d**) 2008 c. 14.

(**e**) Publications gateway reference 04038.

"relevant NHS BSA online gateway" means the service provided for on the NHS BSA website(**a**) which allows pharmacy contractors to submit online the information to in directions 7A(3) and 7B(13);"; and

"working day" means any day from Monday to Friday except Good Friday, Christmas Day or any day that is specified or proclaimed as a bank holiday in England pursuant to section 1 of the Banking and Financial Dealings Act 1971(**b**) (bank holidays).".

New directions 7A and 7B of the 2013 Directions

3. In Part 2 of the 2013 Directions (Advanced services: pharmacy contractors only), after direction 7 (New Medicine Service: ongoing conditions of arrangements) insert the following directions—

National Influenza Adult Vaccination Service: general matters and preconditions to making arrangements

7A.—(1) Until the end of 29th February 2016, the NHSCB must make arrangements for the provision of services as part of the NIAVS with any pharmacy contractor (P) who—

(a) meets Conditions 1 to 6 set out in this direction; 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 NIAVS is to enable pharmacy contractors to participate in arrangements for the administration of intramuscular inactivated influenza vaccine to patients aged 18 and over, in accordance with the National PGD, as part of the national immunisation programme for active immunisation against influenza.

(3) Condition 1 is that P has notified the NHSCB, via the relevant NHS BSA online gateway, of P's intention to provide services as part of the NIAVS.

(4) Condition 2 is that P is 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.

(5) Condition 3 is that—

(a) in respect of any registered pharmacist that P intends to employ or engage as part of the NIAVS, an approved form—

(i) has been completed, in the approved manner, warranting that the pharmacist is competent to perform services as part of the NIAVS, and

(ii) is held (or a copy of it is held) at the pharmacy premises at or from which the services which are part of the NIAVS are to be provided; and

(b) if P is a registered pharmacist, P completes, in the approved manner, an approved form—

(i) warranting that P is competent to perform services as part of the NIAVS, and

(ii) which is held (or a copy of it is held) at the pharmacy premises at or from which the services which are part of the NIAVS are to be provided,

and "approved" for these purposes means approved by the NHSCB.

(6) Condition 4 is that P has in place at the pharmacy premises at or from which the services which are part of the NIAVS are to be provided standard operating procedures —

(a) which have been notified to the pharmacy staff;

(**a**) The website address is www.nhsbsa.nhs.uk.
(**b**) 1971 c. 80.

(b) which explain—

(i) the services to be provided as part of the NIAVS,

(ii) the preconditions for providing the services (in this direction),

(ii) the ongoing conditions under which they have to be provided (in direction 7B), and

(iv) the roles that pharmacy staff may be required to perform as part of the services;

(c) which provide that registered pharmacists who may be required to administer vaccines as part of the service are advised that they should consider being vaccinated against Hepatitis B;

(d) which, if vaccines are to be administered at a care home, set out the standard operating procedures in respect of performing that activity away from the pharmacy premises; and

(e) about which pharmacy staff have received appropriate training, if there is any role that they may be asked to perform as part of the services.

(7) Condition 5 is that, if P is intending to administer vaccines at a care home as part of the NIAVS, P must in respect of each occasion on which P intends to do so—

(a) have notified the general practitioners of the patients to whom P is intending to administer vaccines of P's intention to do so; and

(b) obtain the agreement of the NHSCB to P doing so.

(8) Condition 6 is that P must be able to provide the services which are part of the NIAVS at an acceptable location, and for these purposes "acceptable location" means—

(a) a room for confidential consultations at P's pharmacy premises which is—

(i) clearly designated as a room for confidential consultations,

(ii) distinct from the general public areas of the pharmacy premises, and

(iii) a room where both the person receiving the services which are part of the NIAVS and the registered pharmacist who is to administer the vaccine are able to sit down together and talk at normal speaking volumes without being overheard by any other person (including pharmacy staff),

except that paragraphs (ii) and (iii) do not apply in circumstances where the pharmacy premises are closed to other members of the public; or

(b) if, with the agreement of the NHSCB, P is to provide services as part of the NIAVS at a care home on a particular occasion, then for the purposes of that particular occasion only, a room—

(i) which is at that care home, and

(ii) where both the person receiving the services and the registered pharmacist who is to administer the vaccine are able to sit down together and talk at normal speaking volumes without being overheard by any other person, other than a person whose presence the person receiving the service requests or consents to (such as a carer).

National Influenza Adult Vaccination Service: ongoing conditions of arrangements

7B.—(1) The NHSCB must ensure that arrangements pursuant to direction 7A(1) with a pharmacy contractor (P) include terms equivalent to Conditions A to O set out in this direction.

(2) Condition A is that P has in place and keeps under review at the pharmacy premises at or from which services are to be provided standard operating procedures—

(a) which have been notified to the pharmacy staff (including any changes to the procedures);

(b) which explain—

(i) the services to be provided as part of the NIAVS,

(ii) the preconditions for providing them (under direction 7A),

(iii) the ongoing conditions under which they have to be provided (under this direction), and

(iv) the roles that pharmacy staff may be required to perform as part of the services;

(c) which provide that registered pharmacists who may be required to administer vaccines as part of the service are advised that they should consider being vaccinated against Hepatitis B;

(d) which, if vaccines are to be administered at a care home, set out the standard operating procedures in respect of performing that activity away from the pharmacy premises; and

(e) about which pharmacy staff have received appropriate training, if there is any role that they may be asked to perform as part of the services.

(3) Condition B is that intramuscular inactivated influenza vaccine must only be administered under the arrangements to persons aged 18 and over.

(4) Condition C is that intramuscular inactivated influenza vaccine must only be administered under the arrangements by an appropriately trained registered pharmacist (notwithstanding that other health care professionals may administer the vaccine under the National PGD), and for these purposes, "appropriately trained" is to be construed in accordance with the "additional requirements" and "continued training requirements" in the National PGD.

(5) Condition D is that a registered pharmacist administering the intramuscular inactivated influenza vaccine must adhere to the National PGD and, as appropriate, to the standard operating procedures referred to in condition A.

(6) Condition E is that, in respect of each registered pharmacist who administers vaccines under the arrangements, an approved form—

(a) has been completed, in the approved manner, warranting that the pharmacist is competent to perform services as part of the NIAVS; and

(b) is held (or a copy of it is held) at the pharmacy premises at or from which the services which are part of the NIAVS are to be provided.

(7) Condition F is that, in respect of each occasion on which P intends to administer vaccines at a care home as part of the NIAVS, P must—

(a) notify (if P has not already done so under Condition 5 in direction 7A(7)) the general practitioners of the patients to whom P is intending to administer vaccines of P's intention to do so; and

(b) obtain the agreement of the NHSCB to P doing so.

(8) Condition G is that P must only provide the services which are part of the NIAVS at an acceptable location, and for these purposes, "acceptable location" has the same meaning as in Condition 6 in direction 7A(8).

(9) Condition H is that P must record the patient's consent to the administration of the intramuscular inactivated influenza vaccine (which is a requirement of the National PGD) on the consent form approved for this purpose by the NHSCB.

(10) Condition I is that the NHSCB must terminate the arrangements if it is on notice that P is not, or no longer, 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.

(11) Condition J is that P must ensure that the patient's general practitioner is notified, in the manner approved by the NHSCB (which may include approval of methods of transmission of the information as well as of the form in which the information is to be

transmitted) before the end of the working day after the day on which the patient is vaccinated.

(12) Condition K is that 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 significance,

P or a person employed or engaged by P must ensure that the patient's general practitioner is notified (either as part of the notification in accordance with Condition J or separately).

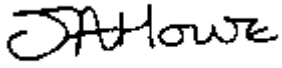
(13) Condition L is that if P is to terminate the arrangements, P must notify the NHSCB of that via the relevant NHS BSA online gateway.

(14) Condition M is that once P has begun to provide services under the arrangements at P's pharmacy premises, then until P or the NHSCB has terminated the arrangements, P must ensure, in so far as is practicable, that services which are part of the arrangements are available at P's pharmacy premises throughout its core opening hours and supplementary opening hours (as defined in the Pharmaceutical Services Regulations(**a**)).

(15) Condition N is that each patient vaccinated under the arrangements must be asked to complete a patient questionnaire, approved for this purpose by the NHSCB, and thereafter P must process the information contained in any completed patient questionnaires in the manner requested by the NHSCB.

(16) Condition O is that NHSCB must terminate any arrangements that are entered into or still in force on 29th February 2016 with effect from the end of 29th February 2016.".

Signed by authority of the Secretary of State for Health



Jeannette Howe
Head of Pharmacy
Department of Health

15th September 2015

(**a**) *See* regulation 2(1) of those Regulations.