



Service specification

Community pharmacy seasonal influenza vaccination advanced service

September 2021

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8.1 Amended cohort definition	Sept 2021	PSNC / NHS England & NHS Improvement		Revisions to allow for vaccination of primary care staff

Equalities and health inequalities statement

Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it
- given regard to the need to reduce inequalities between Patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way where this might reduce health inequalities.

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Summary of changes for 2021/22 and getting started

Summary of key changes for 2021/22

- Standard health inequalities statement added to the document
- Patient cohorts updated to reflect the content of the 2021/22 Annual Flu Letter
- Addition of Annex F to detail the information extracted from electronic clinical records systems via an API to the NHSBSA
- Minor amendments made to include references to JCVI, their determination of cohorts, and their advice about administration of flu alongside other vaccination types
- Minor changes to reflect operational requirements of amendments to the PGD and development of a national protocol

Key next steps for contractors

- Familiarise yourself with this service specification, and changes from the previous flu season
- Ensure your standard operating procedure (SOP) is up to date
- Ensure training of all providing vaccinations on behalf of the pharmacy is up to date, and that support staff are aware of the service and eligible cohorts
- Ensure that all providing vaccinations on behalf of the pharmacy sign the patient group direction (PGD) or relevant national protocol
- Be aware of expected delivery timelines and storage requirements for vaccines
- Ensure you are registered on the MYS platform so that you can submit claims for payment
- Engage with local plans to drive up overall vaccination rates.

The terms within this service specification may be subject to renegotiation during the flu season where significant changes to supply or distribution of vaccines occurs or where patient cohorts are changed.

1. Service description and background

For most healthy people, influenza (flu) is an unpleasant but usually self-limiting disease. However, older people, pregnant women and those with underlying diseases are at particular risk of severe illness if they catch it.

Flu is a key factor in NHS resilience. It impacts on those who become ill, the NHS services that provide direct care as a result, and on the wider health and social care system. The annual immunisation programme helps to reduce unplanned hospital admissions and pressure on A&E. In order to improve access to NHS flu vaccination for eligible patients, NHS England and NHS Improvement has commissioned an advanced service for community pharmacies to provide flu vaccinations since 2015.

During the seasonal flu vaccination campaign period, pharmacy staff will identify people eligible for flu vaccination and encourage them to be vaccinated. This service covers eligible patients aged 18 years and older who are specified in Annex A of this document, based on information in the annual Flu Plan¹.

The service will run from 1 September to 31 March each year.

2. Aims and intended service outcomes

- 2.1 The aims of this service are:
 - a. to sustain and maximise uptake of flu vaccine in at risk groups² by continuing to build the capacity of community pharmacies as an alternative to general practice attendance
 - b. to provide more opportunities and improve convenience for eligible patients to access flu vaccinations

3. Service specification

- 3.1 The patient groups eligible for seasonal flu vaccination under this service, unless contraindicated, are listed in Annex A. Groups eligible for influenza vaccination are based on the advice of the Joint Committee on Vaccination and Immunisation (JCVI) who review the latest evidence on influenza vaccines and recommend the type of vaccine to be offered to patients. The pharmacy contractor is required to offer eligible patients the opportunity of receiving a flu vaccination at the pharmacy. The vaccine is to be administered by an appropriately trained, registered healthcare professional, authorised under the NHS England and NHS Improvement PGD or any relevant emergency national immunisation protocol.
- 3.2 The service is effective from 1 September and runs to 31 March, but focus should be given to vaccinating eligible patients between 1 September and 31 January each year. Eligible patients should be vaccinated as soon as the vaccine is

¹ <u>https://www.gov.uk/government/collections/annual-flu-programme</u>

² The at risk groups and PHE target vaccination levels are set out in the annual Flu Plan <u>https://www.gov.uk/government/collections/annual-flu-programme</u>

available. Widespread immunisation may continue until December in order to achieve maximum impact, but where possible, should be completed before flu starts to circulate in the community. However, flu can circulate considerably later than this and pharmacists should apply clinical judgement to assess the needs of individual patients who are eligible for vaccination under this service to receive immunisation beyond 31 January. This should take into account the level of flu-like illness in the community³ and that immune response following immunisation may take up to 14 days to achieve⁴.

- 3.3 The seasonal flu vaccination to be administered under this service is one of the flu vaccines listed in the NHS England and NHS Improvement, Public Health England and Department of Health and Social Care annual Flu Plan¹.
- 3.4 Pharmacy contractors must ensure that vaccinations offered under this service are provided in line with Immunisation against infectious disease (The Green Book)⁵, which outlines all relevant details on the background, dosage, timings and administration of the vaccine, and disposal of clinical waste⁶. Pharmacy contractors must ensure that vaccination is offered in line with any JCVI guidance on the required interval between, or the co-administration of vaccinations under this service and other vaccination types.
- 3.5 The pharmacy contractor must have a standard operating procedure (SOP) in place for this service, which includes procedures to ensure cold chain integrity. All vaccines are to be stored in accordance with the manufacturer's instructions and all refrigerators in which vaccines are stored are required to have a maximum / minimum thermometer. Readings are to be taken and recorded from the thermometer on all working days. Where vaccinations are undertaken off the pharmacy premises, the pharmacy contractor must ensure that appropriate measures are taken to ensure the integrity of the cold chain.
- 3.6 Each patient being administered a vaccine should be given a copy of the manufacturer's patient information leaflet about the vaccine or be directed to a web-based version of the leaflet.
- 3.7 Prior to vaccination, consent must be sought from each patient. This consent should cover the administration of the vaccine as well as advising the patient of information sharing that will take place for the appropriate recording of the vaccination in their GP practice record. The patient should also be informed that information relating to their vaccination may be shared with NHS England and NHS Improvement. Patient consent should be recorded in the pharmacy's clinical record for the service.
- 3.8 The pharmacy contractor will ensure that a notification of the vaccination is sent to the patient's GP practice on the same day the vaccine is administered or on the following working day. This can be undertaken via post, hand delivery, secure email or secure electronic data interchange. If an electronic method to transfer

³ <u>https://www.gov.uk/government/statistics/weekly-national-flu-reports</u>

⁴ <u>https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19</u>

⁵ <u>https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</u>

⁶ While the Green Book references eligible patient groups for vaccination, community pharmacy staff are to refer to Annex A of this service specification for the groups eligible for this service. The list of eligible patients for this service does not include all those patients outlined in the annual Flu Plan¹ or the Green Book.

data to the relevant GP is used and a problem occurs with this notification platform, the pharmacy contractor should ensure a copy of the paperwork is sent or emailed to the GP practice. Where the notification to the GP practice is undertaken via hardcopy, the national GP Practice Notification Form should be used (see Annex B⁷). The information sent to the GP practice should include the following details as a minimum:

- a. the patient's name, address, date of birth and NHS number (where known)
- b. the date of the administration of the vaccine
- c. the applicable SNOMED CT code see Table 1 below
- d. any adverse reaction to the vaccination and action taken/recommended to manage the adverse reaction
- e. reason for patient being identified as eligible for vaccination (e.g. aged 65 or over, has diabetes).

Any paperwork must be managed in line with 'Records Management Code of Practice for Health and Social Care⁷.

Table 1: Applicable SNOMED CT codes for notification to the GP practice

Code Type	Code	Description
SNOMED CT	955691000000108	Seasonal influenza vaccination given by pharmacist

Where a patient presents with an adverse drug reaction following the initial vaccination and the pharmacist believes this is of clinical significance, such that the patient's GP practice should be informed, this information should be shared with the GP practice as soon as possible.

- 3.9 The pharmacy contractor is required to report any patient safety incidents in line with the Clinical Governance Approved Particulars for pharmacies.
- 3.10 The pharmacy contractor is required to make arrangements for the removal and safe disposal of any clinical waste and personal protective equipment related to the provision of this service (including where the vaccination is undertaken off the pharmacy premises).

4. Training and premises requirements

- 4.1 In order to provide the service, pharmacies must have a consultation room. Vaccinations can be offered in any area of the pharmacy where suitable facilities are available and patient confidentiality is able to be respected. However, the vaccination must take place in the consultation room wherever the patient expresses this preference. The consultation room must comply with the minimum requirements set out below:
 - the consultation room must be clearly designated as an area for confidential consultations

⁷ A standalone version of the GP Practice Notification Form is available on the PSNC website.

- it must be distinct from the general public areas of the pharmacy premises
- it must be a room where both the person receiving services and the pharmacist providing those services are able to sit down together and talk at normal speaking volumes without being overheard by any other person (including pharmacy staff), other than a person whose presence the patient requests or consents to (such as a carer or chaperone)
- it must be a room where infection control standards can be maintained
- 4.2 Vaccinations under this advanced service will usually be carried out on the pharmacy premises, but they can also be undertaken in other suitable locations, such as in the patient's home, a long-stay care home, a long-stay residential facility or community venues (e.g. community centres). Vaccinations should be administered under the supervision of a pharmacist trained in vaccination (including a clear understanding of this service). A record should be maintained of who that person is at each premises at any given time.
- 4.3 The Responsible Pharmacist at the registered pharmacy premises is professionally responsible for the safe delivery of this service. If the Responsible Pharmacist is unable to provide sufficient supervision, for example due to workload or where vaccinations are undertaken off the pharmacy premises, an onsite pharmacist supervising delivery of the service must be linked and work closely with the Responsible Pharmacist and Superintendent Pharmacist through an appropriate governance framework.
- 4.4 Where vaccinations are undertaken off the pharmacy premises, the pharmacy contractor must ensure there is an on-site pharmacist supervising delivery of the service (or delivering the vaccination service themselves) and that vaccinators: are delivering vaccines in accordance with a Patient Group Direction or any relevant emergency national immunisation protocol, as appropriate; have professional indemnity that covers off-site vaccinations; continue to adhere to all professional standards relating to vaccinations; follow appropriate cold-chain storage measures; ensure that the setting used to administer the vaccinations is appropriate (including ensuring patient confidentiality as appropriate); appropriately dispose of any clinical waste or personal protective equipment used during the vaccination process. Additionally, where vaccinations are undertaken in the patient's own home (including a care home), contractors must ensure that vaccinators have a valid DBS certificate.
- 4.5 The pharmacy contractor must ensure that individuals providing the service are competent to do so. Registered pharmacists should demonstrate to the pharmacy contractor that they have the necessary knowledge and skills to provide the service by completing the vaccination services Declaration of Competence (DoC)⁸. The pharmacy contractor must keep on the pharmacy premises copies of each DoC completed by any registered pharmacist that they employ/engage to deliver the service.
- 4.6 The pharmacy contractor must ensure that individuals providing the service are aware of the National Minimum Standards⁹ in relation to vaccination training and are compliant with the training requirements within those Standards that apply,

⁸ The Declaration of Competence is available on the CPPE website: <u>https://www.cppe.ac.uk/doc</u> 9<u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/679824/</u> <u>Training_standards_and_core_curriculum_immunisation.pdf</u>

including the requirements for face to face training and refresher training for injection technique and basic life support (including administration of adrenaline for anaphylaxis). Annual updates should be undertaken to ensure knowledge and practice remain current. Face to face training for injection technique and basic life support (including administration of adrenaline for anaphylaxis) should be undertaken every three years.

- 4.7 The pharmacy contractor must ensure that staff 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. A needle stick injury procedure must be in place.
- 4.8 The pharmacy contractor must ensure that staff involved in the provision of this service are advised that they should consider being vaccinated against Hepatitis B and be advised of the risks should they decide not to be vaccinated.

5. Service availability

- 5.1 The pharmacy contractor should ensure that staff are adequately trained, so as to ensure continuity of service provision.
- 5.2 If the pharmacy temporarily or permanently ceases to provide the service, they should update their NHS website profile to reflect that the service is not available from the pharmacy as soon as possible.
- 5.3 The pharmacy contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible patient shall be excluded or experience particular difficulty in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.

6. Data collection and reporting requirements

- 6.1 The pharmacy contractor must maintain appropriate records to ensure effective ongoing service delivery. The minimum requirements for the information which should be included in a contractor's record of provision of the service to a patient are the mandatory sections indicated within the Flu Vaccination Record Form¹⁰ which is set out in Annex E. Pharmacy contractors can use this form to maintain their record of service delivery or the information can be recorded on an alternative form or in another way, such as an electronic system.
- 6.2 Data recorded via electronic clinical records systems may be shared with the NHSBSA as part of normal payment arrangements (see section 7 below). An application programming interface (API) has been developed to facilitate transfer of this data into the NHSBSA Manage Your Service (MYS) platform to improve payment claim accuracy. Details of the API and the data transferred from clinical systems to MYS are listed at Annex F.

¹⁰ A standalone version of the Flu Vaccination Record Form is available on the PSNC website.

6.3 **For 2021-22 only**, the contractor must manually report via MYS the number of primary care frontline staff, including locums, that have been vaccinated within the 'primary care contractor or frontline staff' cohort. This collection of data is to assure NHS England and NHS Improvement that primary care colleagues are protected as quickly and effectively as possible and are able to continue their vital role in supporting the care of others.

7. Payment arrangements

- 7.1 Claims for payments for this programme should be made monthly, via the MYS platform. Claims will be accepted by the NHSBSA within six months of administration of the vaccination or by 31st August 2022, whichever date is earlier, in accordance with the usual Drug Tariff claims process. Later claims will not be processed.
- 7.2 A fee payment will be made in line with the Drug Tariff determination¹¹ per administered dose of vaccine. This amount includes a contribution in recognition of expenses incurred by community pharmacies in providing this service. These include training and disposal of clinical waste. Such costs are not reimbursed elsewhere within the Community Pharmacy Contractual Framework.
- 7.3 The pharmacy contractor will also be reimbursed for the cost of the vaccine¹². An allowance at the applicable VAT rate will also be paid.
- 7.4 The pharmacy contractor will not be reimbursed or remunerated, under this advanced service, for vaccines administered to patients outside of the eligibility criteria set out in Annex A.

¹¹ Funding for this service will be in addition to and outside of the core CPCF funding.

¹² Any purchase margin by pharmacies relating to the seasonal flu vaccine would be included in the calculation of allowed purchase margin that forms a part of agreed NHS pharmacy funding.

Annex A: Groups included in this advanced service

This service covers those patients most at risk from influenza **aged 18 years and older**, as listed below.

The selection of these eligible groups has been informed by the target list from the annual Flu Plan¹ and Immunisation against infectious disease: The Green Book⁵.

Eligible groups	Further details
All people aged 50 years or over	Including those becoming age 50 years by 31 March 2022.
People aged from 18 years medical condition(s) outline	to less than 50 years of age with one or more serious ed below:
Chronic (long term) respiratory disease, such as severe asthma, chronic obstructive pulmonary disease (COPD) or bronchitis	Asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission. Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD).
Chronic heart disease, such as heart failure	Congenital heart disease, hypertension with cardiac complications, chronic heart failure, individuals requiring regular medication and/or follow-up for ischaemic heart disease.
Chronic kidney disease at stage three, four or five	Chronic kidney disease at stage 3, 4 or 5, chronic kidney failure, nephrotic syndrome, kidney transplantation.
Chronic liver disease	Cirrhosis, biliary atresia, chronic hepatitis.
Chronic neurological disease, such as Parkinson's disease or motor neurone disease or	Stroke, transient ischaemic attack (TIA). Conditions in which respiratory function may be compromised due to neurological disease (e.g. polio syndrome sufferers). Clinicians should offer immunisation, based on individual assessment, to clinically vulnerable individuals including those with cerebral palsy, learning disabilities, multiple sclerosis and related or similar conditions; or hereditary
Learning disability	and degenerative disease of the nervous system or muscles; or severe neurological disability.
Diabetes	Type 1 diabetes, type 2 diabetes requiring insulin or oral hypoglycaemic drugs, diet-controlled diabetes.

Immunosuppression, a weakened immune system due to disease (such as HIV/AIDS) or treatment (such as cancer treatment)	Immunosuppression due to disease or treatment, including patients undergoing chemotherapy leading to immunosuppression, bone marrow transplant, HIV infection at all stages, multiple myeloma or genetic disorders affecting the immune system (e.g. IRAK-4, NEMO, complement disorder). Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day. It is difficult to define at what level of immunosuppression a patient could be considered to be at a greater risk of the serious consequences of influenza and should be offered seasonal influenza vaccination. This decision is best made on an individual basis and left to the patient's clinician. Some immune-compromised patients may have a suboptimal immunological response to the vaccine.
Splenic dysfunction or asplenia	This also includes conditions such as homozygous sickle cell disease and coeliac syndrome that may lead to splenic dysfunction.
Morbid obesity	Adults with a Body Mass Index ≥40kg/m ²
Pregnant women (including those women who become pregnant during the flu season)	Pregnant women aged 18 or over at any stage of pregnancy (first, second or third trimesters).
People living in long-stay residential care homes or other long-stay care facilities	Vaccination is recommended for people aged 18 or over living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. This does not include, for instance, prisons, young offender institutions, or university halls of residence. For the pharmacy service this only applies to those aged 18 or over.
Carers	People aged 18 or over who are in receipt of a carer's allowance, or those who are the main carer of an older or disabled person whose welfare may be at risk if the carer falls ill.
Close contacts of immunocompromised individuals	People who are close contacts, aged 18 and over, of immunocompromised individuals, specifically individuals who expect to share living accommodation on most days over the winter and, therefore, for whom continuing close contact is unavoidable.
Frontline health and social care workers	Health & social care staff, employed by a registered residential care/nursing home or registered domiciliary care provider, who are directly involved in the care of vulnerable patients/clients who are at increased risk from exposure to influenza. Vulnerable means those

	patients/clients in a clinical risk group for flu or who are aged 50 years and over.							
	Primary care contractors (primary medical services, pharmaceutical services, primary dental services or general ophthalmic services) and their frontline staff, including locums. For the avoidance of doubt primary care contractors and frontline staff are those involved in patient- facing frontline provision of NHS primary care services and includes non-clinical reception and counter staff who play an integral part in patient-facing care on a day-to-day basis in primary care settings. Any primary care contractors and their staff not involved in patient-facing frontline provision of NHS primary care services are not included in the definition of frontline staff.							
Hospice workers	Health and care staff, employed by a voluntary managed hospice provider, who are directly involved in the care of vulnerable patients/clients who are at increased risk from exposure to influenza.							
Workers employed through Direct Payments and/or Personal Health Budgets to deliver domiciliary care	Health and social care workers employed through Direct Payments and/or Personal Health Budgets to deliver domiciliary care to patients and service users.							

Annex B: NHS Community Pharmacy Seasonal Influenza Vaccination Service - Notification of administration of flu vaccination to Patient's GP Practice

To (GP practice nam	e)						
Patient name							
Address							
Patient DOB		e known)					
This patient was adr	ninistered a seasonal influenza vaccin	ation on: / /					
	records are complete, you may find it u accination given by pharmacist 1000000108	seful to record this as:					
	□ Aged 65 or over	□ Chronic respiratory disease					
	□ Chronic heart disease	□ Chronic kidney disease					
Eligible patient group (please only tick one		□ Chronic neurological disease					
box, to indicate the	Diabetes	□ Immunosuppression					
reason the patient	□ Asplenia / splenic dysfunction	Pregnant woman					
was initially identified as being eligible)	 Person in long-stay residential care home or care facility 	□ Carer					
	Household contact of immunocompromised individual	☐ Morbid obesity (BMI ≥ 40)					
	□ Aged 50-64 (not in risk group)	□ Learning disability					
	 Employed through Direct Payment or Personal Health Budget 	Primary care contractor or frontline staff					
	Frontline Health & Social care worker	□ Hospice worker					
Additional comments	(e.g. any adverse reaction to the vaccine and action tak	en/recommended to manage the adverse reaction)					
Pharmacy name							
Address							
Telephone							

Annex C: NO LONGER IN USE Annex D: NO LONGER IN USE

Annex E NHS Flu Vaccination Service - Record Form

* indicates sections that must be completed

Patient's details																						
First name*								Τ				Γ										
Surname*																						
Address*																						
Postcode												1		I				<u> </u>	<u> </u>	<u> </u>	1	
Telephone									Τ			Γ										
Date of birth*						Ν	HS	No														
GP																						
practice*																						
Patient's emergency contact									•													
Name																						
٦	Felephone	;																				
Relationship	to patient	t																				
An <u>i</u>	y allergies	5																				
Eligible patie	ent group*		☐ 65 years or over								[Chronic respiratory disease										
			Chronic heart disease								[Chronic kidney disease										
			Chronic liver disease								[Chronic neurological disease										
			Diabetes								[
			Asplenia / splenic dysfunction								[Pregnant woman										
		□ ca	Person in long-stay residential care home or care facility								[Carer										
			Household contact of immunocompromised individual								[☐ Morbid obesity (BMI ≥ 40)										
		50-64 years (not in risk group)									[Learning disability										
	Pa		ploy nt of							Jdg	et	[1	Primary care contractor or frontline staff									
	U wc	Payment of Personal Health Budget									[Hospice worker										

Vaccination details											
Name of vaccine/ manufacturer*	Apply vaccine sticker if available	Date of vaccination*			P	harma	icy sta	ımp			
Batch Number*		Injection site*	□ Left uppe								
Expiry Date*		Route of administration*	□ Intramuso □ Subcutar								
Location (if not in the pharmacy)*	 Patient's home Long-stay care hom Other location (please 		idential facil	ity							
Any adverse effects*											
Advice given and any other notes											
Administered by*	s	Signature*		Registration number							

Annex F: API Data Transfer

Data captured via some electronic clinical records systems (eg PharmOutcomes, Sonar Informatics) is shared directly with the NHSBSA via an API. This allows for greater claims accuracy and ease of claims submission by contractors.

Full details of the API can be found here: Manage your service (MYS) | NHSBSA

The core dataset transmitted by the API includes:

Date of administration ODS code Patient name Patient date of birth Patient NHS number Patient address (including postcode) Patient's GP ODS code, practice name and address (including postcode) Name of vaccine administered

Pharmaceutical Services Negotiating Committee psnc.org.uk

NHS England & NHS Improvement

www.england.nhs.uk