



Community Pharmacy Seasonal Influenza Vaccination Service

Service specification for the Community Pharmacy Seasonal Influenza Vaccination Service in Wales

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This service specification is ongoing and will be reviewed on the specified date (or earlier if needed) in consultation with stakeholders. If any revisions are made, commissioned pharmacy providers will be notified and revised a specification will be issued.

Version history

Version	Changes from previous version	Date
1.0	First approved version	1 September 2024

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Overarching requirements

1. Interpretation

- 1.1. The definitions set out in The Pharmaceutical Services (Clinical Services) (Wales) Directions 2022 (or subsequent iterations of this document) apply to this specification.
- 1.2. *All Wales Pharmacy Database* means the database held by the NHS Wales Shared Services Partnership that contains details of the clinical services that each Pharmacy is commissioned to provide and of the services that individual service providers are accredited to provide. This definition includes any subsequent databases that replace the AWPDP in the future.
- 1.3. *Choose Pharmacy* means the software system developed and managed by Digital Health and Care Wales, where clinical records for this service are maintained, with consultation records being used to generate data for service payment.
- 1.4. *Clinical Supervisor* means a healthcare professional acting in the capacity of a clinical supervisor, as defined by the current national protocol for inactivated influenza vaccine (where one has been issued).
- 1.5. *Contractor* means a person lawfully conducting a retail pharmacy business.
- 1.6. *GP Practice* means a provider of General Medical Services contracted essential services.
- 1.7. *Local Health Board (LHB)* means the Local Health Board that the pharmacy in which the service is being provided is located.
- 1.8. *National Extended Services Management Board (NESMB)* means the Board that has been established by LHBs to facilitate national discussion around community pharmacy extended services. In the event that the name of this board changes, this definition will be taken to mean the replacement board.
- 1.9. *National Clinical Services Accreditation (NCSA)* system means the section of the Health Education and Improvement Wales (HEIW) website (Y Ty Dysgu) where training requirements and packages are made available to individuals working in community pharmacies.
- 1.10. *Patient* means any person in receipt of the service.
- 1.11. *Pharmacist* means a person who is listed in Part 1 of the Register held by the General Pharmaceutical Council under the Pharmacy Order 2010.
- 1.12. *Pharmacist Independent Prescriber* means a pharmacist who is listed in the NHS Wales approved list of Pharmacist Independent Prescribers.

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- 1.13. *Pharmacy* means any premises included on a health board pharmaceutical list where a pharmacist provides drugs or services as part of pharmaceutical services.
- 1.14. *Pharmacy Staff* means any person or persons employed or engaged by a Contractor, who has an ancillary role in respect of, any part of the service but is not a vaccinator (service provider).
- 1.15. *Pharmacy Technician* means a person listed in Part 2 of the Register held by the General Pharmaceutical Council under the Pharmacy Order 2010.
- 1.16. *Pre-registration Foundation Pharmacist* means an individual who holds a General Pharmaceutical Council approved qualification as set out in the Pharmacy Order 2010 and is completing a General Pharmaceutical Council accredited 52-week programme of pre-registration training with an accredited training provide within NHS Wales,
- 1.17. *National Protocol* means a document issued in accordance with the requirements of the Human Medicines Regulations 2012 and approved by the Welsh Ministers that permits vaccination to be carried out by a wider range of individuals who work under the supervision of a competent Clinical Supervisor.
- 1.18. *Service Provider* means a:
 - 1.18.1. suitably trained and competent pharmacist who is supplying and administering the seasonal influenza vaccination in accordance with a valid Patient Group Direction OR
 - 1.18.2. suitably trained and competent pharmacy technician (from 1 October 2024) who is supplying and administering the seasonal influenza vaccination in accordance with a valid Patient Group Direction OR
 - 1.18.3. a pre-registration foundation pharmacist who is administering the seasonal influenza vaccination to patients in accordance with a valid National Protocol or Patient Specific Direction.

2. Scope

- 2.1. This service specification relates to provision of the Seasonal Influenza Vaccination Service as part of the 2024-25 NHS Wales Seasonal Influenza Vaccination programme for eligible patients.

3. Service Aims

- 3.1. To maximise influenza immunisation for patients included in nationally and locally agreed at-risk groups.

4. Service Providers and legal authority to supply and/or administer medicines

- 4.1. The contractor must ensure that vaccinations are supplied and administered only by a service provider permitted to do in accordance with the Human Medicines Regulations 2012. All vaccines are classified as prescription only medicines (POMs) and the supply and administration of a seasonal influenza vaccine described in this service specification must only be provided where there is a relevant legal authorisation in place. This legal authority may be in the form of:
 - 4.1.1. A Patient Group Direction authorised by the relevant local health board
 - 4.1.2. A relevant National Protocol
 - 4.1.3. A Patient Specific Direction issued by a pharmacist independent prescriber.

5. Patient Eligibility

- 5.1. Patients aged 18 years or over who meet one or more of the eligibility criteria for the routine national flu programme in 2024 to 2025 set out in the relevant Welsh Health Circular and are resident (including care home residents,¹ and those of no fixed abode), or registered with a GP practice located, in Wales are eligible to receive this service.
- 5.2. In exceptional circumstances, where the pharmacist is satisfied that the patient would be unable to access care in a timely manner, the service may be provided to other patients who are entitled to NHS services.
- 5.3. Patients may self-refer to the service or be referred to the service by a member of staff in the pharmacy, or another healthcare provider.

¹ Care home residents are eligible to receive the service where appropriate, but providers should be mindful that these individuals may be more complex in terms of their co-morbidities and polypharmacy. Providers must ensure they have sufficient information available to be able to safely provide this service to these individuals.

6. General Principles

- 6.1. Service Providers will not provide this service to themselves, under any circumstances.
- 6.2. Where a Service Provider is asked to provide the service to an individual with whom they have a close personal relationship (e.g., family members, friends, or colleagues), best practice guidance should be followed, as set out by the GPhC in section 4.1 of *In practice: Guidance for pharmacist prescribers*.²
- 6.3. Where the patient's clinical circumstances are outside of the scope of this service, the Service Provider will provide an alternative service in the pharmacy or refer patients to an appropriate service provider who is able to meet their needs.
- 6.4. All care will be as part of NHS Wales and all consultations, and any products supplied under the terms of this service shall be made at no cost to the patient.
- 6.5. The Contractor and service providers employed or engaged by them will offer a user-friendly, non-judgmental, patient-centred, and confidential service.
- 6.6. The Contractor will offer influenza immunisation at the pharmacy, or off-site venue, by a competent service provider, to patients identified as eligible for vaccination by the Welsh Government.
- 6.7. The Contractor will ensure that the influenza vaccination service is offered to eligible patient cohorts from the start dates set out in the current Welsh Health Circular (see 6.7.1 and 6.7.2): unless the relevant health board agrees an alternative programme start date with the contractor which is confirmed in writing.
 - 6.7.1. The main adult vaccination programme should begin from the 1 October and be delivered at pace with an expectation that all eligible patients should be offered a vaccination by early December.
 - 6.7.2. During September (from 1 September), contractors should consider vaccination of pregnant women only, where delaying until October would mean they risk missing out on vaccination
 - 6.7.3. Where the contractor does not have confidence that it will be possible to vaccinate their entire eligible adult cohort between October and early December, (with the exception of pregnant women described in 6.7.2) they should contact their health board to discuss options. Any variation to the start date of the adult vaccination programme will be agreed with the health board and confirmed in writing.

² <https://www.pharmacyregulation.org/sites/default/files/document/in-practice-guidance-for-pharmacist-prescribers-february-2020.pdf>

- 6.8. The Contractor shall promote influenza immunisation to eligible patients including providing information (which may be verbal or written) regarding the availability of influenza vaccination from their GP practice and from the pharmacy.
- 6.9. The Contractor should inform local GP practices as soon as possible that they intend to provide the Seasonal Influenza Vaccination Service during the relevant season.
- 6.10. Where patients indicate that they have already booked an appointment with their GP practice for vaccination, they should be encouraged to keep this appointment.

7. Consultations

- 7.1. All patients requesting vaccination under this service will be assessed for their eligibility (see clauses 5 and 6.7) and the clinical appropriateness of the selected vaccination before the vaccine is administered.
- 7.2. The Service Provider will only vaccinate a patient where they have a valid legal authority in place for the supply and administration of the vaccination for that patient. This may be through one of:
 - 7.2.1. A Patient Group Direction (PGD) enabling pharmacists and pharmacy technicians to supply and administer vaccines where they meet the PGD requirements for characteristics of staff and have their name included in the All Wales Pharmacy Database as a service provider.
 - 7.2.2. A Patient Specific Direction –enabling pre-registration foundation pharmacists who and have their name included in the All Wales Pharmacy Database as a service provider and meet the requirements for characteristics of staff to supply and administer vaccines where:
 - 7.2.2.1. the patient has been individually assessed as suitable for vaccination by a competent³ Pharmacist Independent Prescriber who has their name included in the All Wales Pharmacy Database as a seasonal influenza vaccination service provider;
 - 7.2.2.2. there is a specific written direction to administer the vaccination to the individual and

³ pharmacist prescribers must prescribe only within the limits of their knowledge, skills and clinical competence [In practice: Guidance for pharmacist prescribers \(pharmacyregulation.org\)](https://pharmacyregulation.org/in-practice-guidance-for-pharmacist-prescribers)

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- 7.2.2.3. the Pharmacist Independent Prescriber is present at the time of vaccination); and
- 7.2.2.4. the registration number of Pharmacist Independent Prescriber who has authorised the administration is recorded within the Choose Pharmacy record for each patient.
- 7.2.3. A National Protocol – enabling pre-registration foundation pharmacists who and have their name included in the All Wales Pharmacy Database as a service provider and meet the requirements for characteristics of staff to supply and administer vaccines where:
 - 7.2.3.1. A valid National Protocol is in place; and
 - 7.2.3.2. the patient has been individually assessed as suitable for vaccination by a competent Pharmacist Independent Prescriber⁴ or another pharmacist or pharmacy technician who can operate under a PGD and who has their name included in the All Wales Pharmacy Database as a seasonal influenza vaccination service provider;
 - 7.2.3.3. there is a competent⁴ Clinical Supervisor present at the time of vaccination; and
 - 7.2.3.4. the Service Provider must have been signed off as competent using a [suitable flu vaccinator competency assessment tool](#)⁵ by a competent⁵ Clinical Supervisor.
 - 7.2.3.5. been authorised by name as an approved person under the current terms of the protocol; and
 - 7.2.3.6. the GPhC registration number of the Clinical Supervisor in place at the time of vaccination is recorded within the Choose Pharmacy record for each patient.
- 7.3. When providing vaccination in the pharmacy, or off-site, the Contractor shall ensure that the service is only provided from an area that meets the criteria set out in clause 12.2.

⁴ For the purposes of this specification, the Clinical Supervisor must be a pharmacist who is trained and competent in all aspects of the protocol and have their name currently included in the All Wales Pharmacy Database as a service provider for the seasonal influenza vaccination service. The Clinical Supervisor must be present and take overall responsibility for provision of vaccination under the protocol at all times and be identifiable to patients.

⁵ For example <https://www.gov.uk/government/publications/flu-immunisation-training-recommendations>

- 7.4. When providing vaccinations off-site, the Contractor must ensure that each of the points listed in section 9 are considered. Further, they must ensure that there are appropriate procedures in place to enable the safe transfer of vaccines (including maintenance of the cold chain), patient records, and clinical waste and sharps between the pharmacy and the premises where the service is provided.
- 7.5. To facilitate the provision of “flu clinics” by contractors, the service may be provided in the pharmacy or off-site, outside of normal pharmacy opening hours. In all cases, the standards for service provision remain as laid out in this document.
- 7.6. The Contractor will ensure that all service providers involved in providing this service have been offered vaccination against Hepatitis B.

8. Pharmacists and pharmacy technicians with needle phobia

- 8.1. The following considerations must be made where a pharmacist or pharmacy technician has needle phobia:
 - 8.1.1. Before arranging a locum booking/employment, both the Contractor and pharmacist or pharmacy technician with needle phobia must consider the ease with which a user of the pharmacy would be able to access influenza vaccination from another service provider locally if it were not to be available in this pharmacy. For example, in locations that are more rural, other services are less likely to be available and there is an increased risk that an individual requesting the service would not be able to access it in a timely manner.
- 8.2. Pharmacist Independent Prescribers with a needle phobia may consider completing training and becoming accredited for the service in order to support other pharmacy staff to administer vaccines under a relevant Patient Specific Direction or National Protocol.

9. Vaccination off premises

- 9.1. When providing vaccination services away from the pharmacy premises the Contractor must ensure that information governance, infection prevention and control, and clinical governance are carefully considered to ensure the safe and effective delivery of the service. In particular, the following must be in place:
 - 9.1.1. Appropriate transportation arrangements to maintain the vaccine cold chain in line with the requirements of the relevant Summary of Product Characteristics; and
 - 9.1.2. Immunisation will be carried out by a Service Provider meeting the accreditation requirements set out in section 11; and
 - 9.1.3. Appropriate hygiene and infection prevention measures will be in place; and

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- 9.1.4. Appropriate personal protective equipment will be available; and
- 9.1.5. Appropriate arrangements are in place for clinical record documentation; and
- 9.1.6. Appropriate arrangements for the management of anaphylaxis will be in place, including adrenaline and emergency telephone access; and
- 9.1.7. Appropriate arrangements for the management of clinical waste will be in place (including transportation back to the pharmacy) and that these are in line with relevant hazardous waste regulations; and
- 9.1.8. Suitable indemnity insurance arrangements will be in place; and
- 9.1.9. Information is provided to the patients GP practice in a timely fashion; and
- 9.1.10. Choose Pharmacy flu vaccination records are updated on the same or, where Choose Pharmacy cannot be used at the off-site location, no later than the next working day following vaccination.

10. Consultation records

- 10.1. Details of all consultations provided under this service will be recorded in the relevant module of the Choose Pharmacy system during, or immediately following, the consultation with the patient.
- 10.2. Where the Choose Pharmacy system is temporarily unavailable owing to reasons beyond the control of the Contractor, details of the consultation will be recorded on paper forms and transferred to the relevant module as soon as possible, and where this would be later than the next working day, the Local Health Board must be notified.
- 10.3. An electronic summary will be automatically forwarded to the patient's GP practice following each entry consultation that is entered in the Choose Pharmacy system.
- 10.4. Where the Choose Pharmacy system is unable to transmit the electronic summary, (such as where the patient is registered with a GP practice in England), details of the consultation must be printed and forwarded as soon as practicable, and in all cases within 5 working days, to the person with whom the patient is registered for General Medical Services.

11. Training and accreditation requirements

Before providing this service, Service Providers will ensure that they:

- 11.1. have completed the required training set out on the HEIW [Ty Dysgu platform](#) including National Clinical Services Accreditation (NCSA) , and any requirements for initial or refresher vaccination and basic life support training; and

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- 11.2. have successfully completed the Disclosure and Barring Service (DBS) check process with NHS Wales Shared Services Partnership, including any approvals required where the check returns a record entry; and
- 11.3. have submitted one of the following to the NHS Wales Shared Services Partnership:
 - 11.3.1. a Patient Group Direction declaration (to be completed by pharmacists and pharmacy technicians supplying and administering vaccinations under a Patient Group Direction) or
 - 11.3.2. the [Seasonal Influenza Alternative Service Provider Declaration Form](#) (to be completed by pre-registration pharmacists administering vaccinations under a National Protocol of Patient Specific Direction).
- 11.4. have received confirmation that their name is included in the All-Wales Pharmacy Database.
- 11.5. Service Providers must be competent to assess a patient's capacity to understand the nature and purpose of the treatment they will be offered/receive and that they have the capacity to give or refuse consent to treatment.

12. Contractor responsibilities

- 12.1. Contractors wishing to provide this service will indicate this through submission of a Premises [Listing](#) Form to the NHS Wales Shared Services Partnership.
- 12.2. Other than with prior agreement of their Local Health Board, the Contractor will ensure that the service is provided from a consultation area of the pharmacy which:
 - 12.2.1. is a clearly designated area for confidential discussion which is distinct from the general public areas of the pharmacy; and
 - 12.2.2. is an area where both the patient receiving the service and the Service Provider can sit down together and talk at normal speaking volumes without being overheard by any person, including other pharmacy staff; and
 - 12.2.3. is an area which ensures the dignity and privacy of the patient is maintained; and

- 12.2.4. is of an appropriate size and layout to facilitate the provision of all aspects of the service being provided in accordance with accepted standards of safe clinical practice including the management of any potential adverse effect, including provision of basic life support and anaphylaxis management where relevant;⁶ and
 - 12.2.5. has suitable facilities to ensure adequate hand hygiene can be maintained; and
 - 12.2.6. has suitable arrangements in place with their Local Health Board for the safe disposal of sharps and clinical waste; and
 - 12.2.7. has a network connection that meets the requirements to be able to access the Choose Pharmacy system
 - 12.2.8. has appropriate computer equipment that can be used to access the Choose Pharmacy system from within the consultation area.
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- 12.3. The Contractor will ensure that pharmacy staff involved in delivery of this service have knowledge of, and/or relationships with, other appropriate service providers such that patients with ongoing needs can be referred effectively.
 - 12.4. Notwithstanding exceptional circumstances where the system is not available owing to circumstances beyond the control of the contractor, the contractor will ensure that the Choose Pharmacy system is accessible to all Service Providers, such that they can maintain contemporaneous records for each consultation.
 - 12.5. The Contractor must ensure that appropriate infection prevention and control policies are in place, including cleaning between patients, where appropriate.
 - 12.6. The Contractor will ensure that appropriate indemnity insurance arrangements are in place for any staff providing the service, pursuant to their individual roles and responsibilities.
 - 12.7. The Contractor will ensure that a standard operating procedure is in place at the pharmacy for the provision of the service.
 - 12.8. The Contractor will ensure that all standard operating procedures and any guidance or instructions issued align to the provisions in this service specification and that there are no additional restrictions, limits, or directions preventing Service Providers from exercising their professional autonomy in delivering this service.

⁶ Where the consultation area itself is not of a size or layout to allow BLS to be administered, arrangements must be in place to ensure that this can be done in the immediate vicinity of the consultation area, whilst considering the dignity and privacy of the patient

- 12.9. The Contractor will have appropriate business continuity arrangements in place to maintain service continuity and take all reasonable steps to ensure that patients are able to access this service in the event of temporary suspension of pharmaceutical services in the pharmacy
- 12.10. Where a patient requests the Seasonal Influenza Vaccination service, it will be provided at time that is mutually agreeable to the patient and the Contractor during the current season.
- 12.11. The Contractor will have awareness of, and ensure the service is provided in accordance with, any relevant nationally or locally agreed standards this will specifically include, but not be limited to, having in place procedures for dealing with needle stick injuries, syncope and resuscitation.
- 12.12. The Contractor will participate in any reasonable publicity of the service required by the Local Health Board or Welsh Government.
- 12.13. Where publicity material not directly supplied by the Health Board or Public Health Wales is used to promote the service, such materials as are developed by a contractor must clearly state that the service is funded by NHS Wales, include the NHS Wales logo, describe the service accurately, and adhere to all relevant professional standards. Where a Local Health Board believes that contractor-produced materials do not conform to these requirements, the contractor must cease using them.
- 12.14. Unless explicitly stated within the individual component details, Contractors are responsible for procuring all consumables and equipment required for service provision.
- 12.15. All equipment or tests used in provision of this service must be used in accordance with the manufacturer's instructions.
- 12.16. Where required, maintenance, and quality assurance/validation of equipment or tests must be undertaken in line with the manufacturer's instructions and all relevant statutory and regulatory requirements relating to equipment and tests must be adhered to.
- 12.17. Contractors will co-operate with, and support their staff to participate in, any reasonable review of the service required by their local health board, or the Welsh Government.
- 12.18. Contractors will report any clinical incidents that occur through the provision of this service via the Once for Wales Concerns Management System (Datix Cymru).
- 12.19. Suspected adverse events will be reported using the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card Scheme, where appropriate.

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- 12.20. Contractors will ensure that the service is provided only by service providers who meet the requirements specified in Section 11, are competent to provide the service, and have met all legal and accreditation requirements pertinent to provision.
- 12.21. Contractors will ensure that service providers have the appropriate legal authority in place to vaccinate individual patients.
 - 12.21.1. Where the contractor uses more than one legal authority to supply and administer vaccines within this service, the contractor must ensure that all staff understand the legal authorities in place and how and when they should be used.
 - 12.21.2. Where multiple person models are used (National Protocols and Patient Specific Directions), contractors must ensure that all elements of the protocol are complied with, in the provision of vaccination to each individual.

13. Service Provider responsibilities

- 13.1. When conducting consultations, patients must be offered a chaperone in line with the contractor's Chaperone Policy.
- 13.2. Service providers will ensure that indemnity insurance is in place that covers their roles and responsibilities with respect to provision of the service.
- 13.3. Where necessary, Service Providers should take steps to confirm the identity of individuals wishing to register with a service.
- 13.4. Service Providers will use their professional judgement to consider and, where appropriate, act on any child protection and or safeguarding issues coming to their attention in the course of providing the service.
- 13.5. Service providers must ensure that
 - 13.5.1. There is a valid legal authority in place for vaccination of each patient;
 - 13.5.2. They meet the requirements for characteristics of staff set out in the relevant legal authority;
 - 13.5.3. They have completed the required training, accreditation and competency assessment set out in the relevant legal authority;
 - 13.5.4. The appropriate legal authority is used to supply and administer the vaccine to each patient.

See clause 7.2 and section 11 for further detail.

14. Monitoring and review

- 14.1. Monitoring and review of service delivery will be undertaken during the health board contract monitoring visits and at other times, where deemed necessary by the Local Health Board.

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- 14.2. Post Payment Verification (PPV) will also be undertaken by health board officers, or its representatives as required to meet external audit requirements and ensure proper use of public funds.
- 14.3. Where such monitoring and review activity identifies discrepancies, further steps may be taken as set out in The National Health Service (Pharmaceutical Services) (Wales) Regulations 2020.

15. Fees

Details of all fees payable under this service are set out in [Part VIE](#) of the Drug Tariff.

16. Review, Variation and Termination

- 16.1. Variation to the service specification will be made in consultation with Community Pharmacy Wales; and must be authorised by the National Extended Services Management Board (NESMB).
- 16.2. Contractors will be notified of any variations to the service specification in writing. No variation to the specification will be made until 30 days after that notice is received, other than where it is clinically or legally necessary to do so;
- 16.3. Contractors, as signatories to the Premise Listing Form, may cease to provide the service by informing NWSSP by email nwssp-primarycareservices@wales.nhs.uk giving 90 days notice. The service will be terminated 90 days after that notice is received