Classification: Official



Community Pharmacy Outreach Enhanced Service Specification

COVID-19 vaccination programme: 1 April 2025 to 31 March 2026

Version 1.0



Equalities and health inequalities statement

"Promoting equality and addressing health inequalities are at the heart of NHS England'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 ensuring that services are provided in an integrated way where this might reduce health inequalities."

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Agreement between the parties

- A The Commissioner commissions the Pharmacy Contractor to provide Outreach COVID-19 vaccinations to Patients in accordance with this ES.
- B The Pharmacy Contractor agrees to provide this ES, including any variations and updates from the Commencement Date until the End Date, unless terminated earlier in accordance with the terms of this ES.
- C The Pharmacy Contractor shall provide the service in accordance with the terms of this ES and in full compliance with its Terms of Service or Local Pharmaceutical Services contract terms, as applicable to the Pharmacy Contractor.

Commencement Date	1 April 2025
Commissioner	NHS England
	Address for service of notice:
	[Insert]
Pharmacy Contractor	[Insert Pharmacy Contractor's name (as set out in the relevant pharmaceutical list) and address]
National Enhanced Service (ES)	Community Pharmacy Outreach Enhanced Service: COVID-19 Vaccination programme: 1 April 2025 to 31 March 2026
Designated Site	[insert address of the Designated Site]
Service Payment	means the payment set out at paragraph 15
JCVI Cohorts to be vaccinated	[5-11 years and] [12-15 years and] [16-17 years and] [18 years+] means the ages of Patients that the Pharmacy

Contractor may vaccinate when announced and authorised by the Commissioner

- D This ES is specific to the Pharmacy Contractor and the Pharmacy Contractor may not sub-contract, assign, novate or otherwise seek to transfer any of its rights or obligations under this ES to any other party without the prior written permission of the Commissioner.
- E Except where it is expressly stated to the contrary, this ES does not give rise to any rights enforceable by any person who is not a party to it.

Signed for and on behalf of the	Signed for and on behalf of the
Commissioner:	Pharmacy Contractor:
Signature	Signature
Name	Name
Job title	Job title
Date	Date

1. Introduction

- 1.1 The Pharmacy Contractor has submitted a Tender Response Document and has been awarded this arrangement to provide Vaccination Outreach Services and the administration of vaccinations services in accordance with this Enhanced Service (ES¹). This ES is subject to amendments from time to time as the COVID-19 vaccination programme develops and is subject to Ministerial Decision.
- 1.2 This ES is a core national specification setting out minimum requirements that should not be varied locally. The tender response document for the local [procurement exercise], however, reflects the specific needs of that area that the Pharmacy Contractor's services will meet.
- 1.3 This ES is an Outreach Coronavirus Vaccination Service which is an enhanced service referred to in Direction 14 of the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 as amended.
- 1.4 An ES is designed to cover enhanced aspects of vaccination awareness, education and delivery, all of which are beyond the scope of essential services. No part of this ES specification by commission, omission or implication defines or redefines essential services.
- 1.5 A key aim of this ES is to maximise vaccination awareness and education through outreach services and, as a consequence of this, build trust in vaccinations and maximise the uptake of COVID-19 and seasonal influenza vaccinations (together with other vaccinations which the Patient is eligible). The services are to be provided from a variety of settings and effectively utilise available staff across healthcare providers.

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¹ Section 7A functions are arrangements under which the Secretary of State delegates to NHS England responsibility for certain elements of the Secretary of State's public health functions, which add to the functions exercised by NHS England under the National Health Service Act 2006 ("the 2006 Act"). They are made under section 7A of the 2006 Act. NHS England is responsible and accountable for the discharge of all the Section 7A functions. This ES is a core national specification that should not be changed or varied locally.

2. Definitions

- 2.1 This specification is referred to as this "ES".
- 2.2 In this ES:
 - 2.2.1 "Commencement Date" means [1 April 2025];
 - 2.2.2 "Commissioner" means NHS England;
 - 2.2.3 "CQC" means the Care Quality Commission;
 - 2.2.4 "Designated Site" means the premises nominated by a Pharmacy Contractor and approved by the Commissioner in accordance with the Designation Process as the premises to which the COVID-19 vaccine will be delivered and where the COVID-19 vaccine must be stored overnight;
 - 2.2.5 "Designation Process" means the COVID-19 Assurance and Site Designation process set out in the <u>COVID-19 vaccination</u> programme: 1 April 2025 to 31 March 2026 Site Sign-up Process for Suppliers document which is undertaken to ensure that the Designated Site meets the specified site criteria and which may be updated and amended as required from time to time and is an integral part of this ES;
 - 2.2.6 "End Date" means 31 March 2026 unless terminated earlier in accordance with paragraph 3.12 or otherwise in accordance with this ES or extended in accordance with paragraph 3.2;
 - 2.2.7 "Expected COVID-19 Vaccination Administration Service
 Commencement Date" means the date from which the
 administration of COVID-19 vaccinations shall commence and
 which shall be following an announcement by the Commissioner;
 - 2.2.8 "GPhC" means the General Pharmaceutical Council;
 - 2.2.9 "Green Book" means the Green Book: Immunisation against infectious disease published by UKHSA, which has the latest information on vaccines and vaccination procedures for all the vaccine preventable infectious diseases that may occur in the UK. For COVID-19 the appropriate chapter is available at the following

website which is updated from time to time: https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a;

- 2.2.10 "Healthcare Premises" means any location that falls into one or more of these categories:
 - 2.2.10.1. a place to which people are admitted for the purpose of receiving a regulated activity to meet healthcare needs (for example a hospital, day surgery unit);
 - 2.2.10.2. a place in which people live as their main or sole place of residence or in which they are educated, and they receive care or treatment there (for example, a care home);
 - 2.2.10.3. an urgent care facility (for example, a walk-in centre);
 - 2.2.10.4. the premises where a primary care provider carries on regulated activity other than vaccinations (for example a GP, pharmacy, out-of-hours, dental, community substance misuse service or sexual assault referral centre);
 - 2.2.10.5. the premises from which a registered provider organises or manages care that is delivered to people in their homes (for example a domiciliary care (home care), supported living or shared lives service);
 - 2.2.10.6. a place from where an ambulance or patient transport service is managed;
 - 2.2.10.7. a stand-alone permanent diagnostic or screening facility; or
 - 2.2.10.8. a place from where urgent remote clinical advice and triage is managed (for example, an NHS 111 service);
- 2.2.11 "JCVI" means the Joint Committee on Vaccination and Immunisation:
- 2.2.12 "JCVI Cohorts" means the cohorts of Patients referenced by JCVI advice;

- 2.2.13 "MHRA" means the Medicines and Healthcare products Regulatory Agency;
- 2.2.14 "Ministerial Decision" means a decision issued by the Secretary of State for Health and Social Care;
- 2.2.15 "National Booking Service" or "NBS" means the national system used by Patients to book coronavirus (COVID-19) vaccination appointments;
- 2.2.16 "Patient" means those patients eligible to receive the vaccination by their inclusion in a JCVI Cohort which has been announced and authorised by the Commissioner as eligible for vaccination by the Pharmacy Contractor and as set out at paragraph 7;
- 2.2.17 "Pause" means a pause to the requirement for the administration of COVID-19 vaccinations and the Vaccination Outreach Services as set out at paragraph 3.7;
- 2.2.18 "Pharmaceutical List" means the pharmaceutical list prepared, maintained and published by NHS England pursuant to regulation 10(2)(a) of the Pharmacy Regulations;
- 2.2.19 **"Pharmaceutical Services"** has the meaning set out in the Pharmacy Regulations;
- 2.2.20 "Pharmacy Contractor" means the pharmacy contractor who is a provider of Pharmaceutical Services who has submitted a Tender Response Document, been awarded and has agreed with the Commissioner to deliver this ES;
- 2.2.21 "Pharmacy Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended;
- 2.2.22 "Point of Care System" means a clinical system that has been assured by the Commissioner to record COVID-19 vaccination events;
- 2.2.23 "Private Patients" means any non-NHS Patients;

- 2.2.24 "Seasonal Influenza AS" means the Seasonal Influenza Vaccination Programme Service Specification for 2025/26 which is capable of being entered into by the Pharmacy Contractor during the Term;
- 2.2.25 "SPS" means the Specialist Pharmacy Service;
- 2.2.26 "Tender Response Document" means the response to the COVID-19 Vaccination Site Selection Process Guidance whereby the Pharmacy Contractor is awarded this arrangement to deliver services under this ES;
- 2.2.27 "Term" means the period from the Expected COVID-19 Vaccination Administration Services Commencement Date to the End Date;
- 2.2.28 "Terms of Service" means the terms of service that the Pharmacy Contractor is required to adhere to as set out in the Pharmacy Regulations and this ES;
- 2.2.29 "UKHSA" means the UK Health Security Agency;
- 2.2.30 **"Vaccination Outreach Services**" means the services as described at paragraph 7.1 [insert]; and
- 2.2.31 "Vaccination Outreach Services Commencement Date" means [insert date].
- 2.3 In this ES, words importing the singular include the plural and vice versa.
- 2.4 References to any body, organisation or office include reference to its applicable successor from time to time.

3. Duration

- 3.1 The Pharmacy Contractor shall provide this ES in accordance with its terms from the Commencement Date to the End Date unless it is terminated in accordance with paragraph 3.12.
- 3.2 The Commissioner may, on no less than 21 days notice to the Pharmacy Contractor and no later than 21 days before the End Date, agree with the Pharmacy Contarctor to extend the term by up to 12 months.

- 3.3 The Vaccination Outreach Services shall commence with effect from Vaccination Outreach Services Commencement Date.
- 3.4 The administration of COVID-19 vaccinations shall commence with effect from the Expected COVID-19 Vaccination Administration Commencement Date.
- 3.5 Where the Pharmacy Contractor is unable to commence the Vaccination Outreach Services by the Vaccination Outreach Services Commencement Date, the Pharmacy Contractor must notify the Commissioner as soon as reasonably possible.
- 3.6 The Commissioner may agree with the Pharmacy Contractor an extension not exceeding 2 weeks following the Vaccination Outreach Services Commencement Date to commence the Vaccination Outreach Services. Failure to begin the Vaccination Outreach Services within the agreed timeframe will result in termination of the ES on a date to be notified by the Commissioner to the Pharmacy Contractor.
- 3.7 Where there is (in the reasonable view of the Commissioner) significantly reduced Patient demand for the administration of COVID-19 vaccinations, there is unacceptable wastage of the COVID-19 vaccine, the arrangements do not represent acceptable value for money and/or the Commissioner determines that there is no longer a need for the Vaccination Outreach Services, the Commissioner may require the Pharmacy Contractor to suspend the COVID-19 vaccination services (a "Pause").
- 3.8 Where the Pharmacy Contractor does not agree to the Pause, it may provide evidence to the Commissioner detailing that there is not a significantly reduced Patient demand for the administration of COVID-19 vaccinations, there is not unacceptable wastage of the COVID-19 vaccine, the arrangements represents acceptable value for money and/or there is a need for the Vaccination Outreach Services and the Commissioner shall, acting reasonably, reconsider whether it remains appropriate to continue with the Pause.
- 3.9 During a Pause, the Pharmacy Contractor shall not administer COVID-19 vaccinations and/or shall not provide the Vaccination Outreach Services and shall not be entitled to claim or receive any payment for the administration of COVID-19 vaccinations except in respect of the vaccination services which took place prior to the date on which the Pause occurred, unless in the case of unavoidable and limited costs which have

been exceptionally agreed with the Commissioner in advance of such costs being incurred.

- 3.10 While the services are Paused, the Commissioner and the Pharmacy Contractor shall use all reasonable efforts to ensure that no further Patients are referred to the Pharmacy Contractor for the services under this ES and should direct Patients to available services, as appropriate.
- 3.11 It is a condition of this ES that the Pharmacy Contractor must also deliver each Seasonal Influenza AS available during the Term. The offer of coadministration of the COVID-19 and seasonal influenza vaccinations, subject to vaccine availability, must be made to each eligible Patient the Pharmacy Contractor is able to vaccinate in accordance with the Seasonal Influenza AS, this ES and recommendations for co-administration in the Green Book.
- 3.12 This ES may be terminated on any of the following events:
 - 3.12.1 automatically when the COVID-19 vaccination programme or the outreach programme comes to an end (and which shall be announced by the Commissioner);
 - 3.12.2 automatically where the Pharmacy Contractor has not offered vaccinations under the Seasonal Infleunza AS for the preceding 56 days or otherwise agreed by the Commissioner and unless the seasonal influenza vaccination programme has come to an end (as set out in the Seasonal Influenza AS);
 - 3.12.3 automatically on the same date as the termination of the Pharmacy Contractor's Seasonal Influenza AS, where the termination of the Seasonal Influenza AS is by the Commissioner or the Practice on notice:
 - 3.12.4 by the Commissioner providing not less than 42 days' written notice to the Pharmacy Contractor;
 - 3.12.5 by the Pharmacy Contractor providing not less than 42 days' written notice to the Commissioner, unless otherwise agreed with the Commissioner;
 - 3.12.6 immediately on removal of either the Pharmacy Contractor from a Pharmaceutical List or, if there are more than one premises in

- relation to the Pharmacy Contractor, the removal of the Designated Premises from a Pharmaceutical List at or from which the Pharmacy Contractor provides the ES pursuant to this ES; or
- 3.12.7 immediately where the Pharmacy Contractor does not commence the Vaccination Outreach Services and/or the administration of vaccinations in accordance with paragraph 3.3 to 3.6.
- 3.13 Details of this ES and the wider COVID-19 vaccination programme can be found at https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/.

4. Vaccine supply and availability

- 4.1 The Pharmacy Contractor will be provided with COVID-19 vaccines to deliver this ES. The vaccine must not be used to administer vaccinations to Private Patients. The Pharmacy Contractor and the Commissioner may agree to the vaccination or prioritisation of particular JCVI Cohorts.
- 4.2 The Pharmacy Contractor should understand that the COVID-19 vaccine availability and supply may be challenging and may be constrained and is subject to change over time.
- 4.3 The Commissioner may (acting reasonably) need to make allocation decisions regarding the COVID-19 vaccine during the Term of this ES. Allocation decisions could include prioritising providers or the use of a particular type of COVID-19 vaccine.
- 4.4 The Commissioner will, where possible, arrange supply to meet local population need from providers that are best placed to meet that need and to enable the vaccination delivery as set out at paragraph 4.1.
- 4.5 The Pharmacy Contractor must provide support in relation to stock forecasting, use and ordering of COVID-19 vaccine as requested by the Commissioner.
- 4.6 The Pharmacy Contractor must minimise COVID-19 vaccine wastage including through how activity is planned and support the high uptake of vaccinations where possible through the provision of the Vaccination Outreach Services.

5. Collaboration requirements

- 5.1 The Pharmacy Contractor will work together with others in a collaborative manner and in accordance with the collaboration requirements of this ES to deliver all aspects of this specification.
- 5.2 The Pharmacy Contractor will:
 - 5.2.1 comply with any reasonable request for information from the Commissioner relating to the provision of the services pursuant to this ES:
 - 5.2.2 have regard to all relevant guidance published by the Commissioner or referenced within this ES;
 - 5.2.3 comply with all clinical protocols giving explicit consideration to contra-indications and any guidance around concurrent adminstration of vaccinations (e.g pneumococcal, pertussis or influenza vaccinations);
 - 5.2.4 take reasonable steps to provide information (supplementary to national communications) to Patients about the services pursuant to this ES, including information on how to access the services and any changes to them; and
 - 5.2.5 ensure that it has in place suitable arrangements to enable the lawful sharing of data to support the delivery of the services, business administration and analysis activities.

6. Site designation and premises requirements

- 6.1 The Pharmacy Contractor will have nominated and have access to the Designated Site as set out in its Tender Response Document.
- 6.2 The Vaccination Outreach Services and the administration of COVID-19 vaccinations may take place:
 - 6.2.1 [insert details of the communities, roving models etc that the Region is commissioning as per the competition/prospectus].
- 6.3 Where the Designated Site is not the registered pharmacy, it will be classed as an associated premises to the registered pharmacy and be subject to GPhC regulation including the standards for registered pharmacies.

- Any amendments, additions or the removal of the Designated Site and/or any of the communities set out in paragraph 6.2 shall only be permitted with the agreement (in writing) of the Commissioner.
- Where there is a change to the registered pharmacy premises of the Pharmacy Contractor, which may or may not be the Designated Site, the Pharmacy Contractor must notify the Commissioner. Where the registered pharmacy premises are the Designated Site, approval from the Commissioner of a change to the Designated Site will be required.
- 6.6 From the Commencement Date to the End Date, the Commissioner shall be entitled to access and inspect the Designated Site and any premises from which the Community Pharmacy provides the Vaccination Outreach Services and/or the administration of the vaccinations to undertake an assessment of the readiness of those premises and the Pharmacy Contractor to deliver the services as set out in this arrangement or to ensure that the services are being delivered in accordance with this arrangement. The Commissioner may authorise other organisations to act on its behalf in undertaking such an assessment visit. The Pharmacy Contractor will be notified by the Commissioner in advance of any visit and the details of who will undertake that visit.
- 6.7 COVID-19 Vaccinations may only be offered to Patients in accordance with Paragraph 7.
- 6.8 Vaccinations can be offered in any area where suitable facilities are available, infection control standards can be maintained, and patient confidentiality and dignity is able to be respected.
- 6.9 The Pharmacy Contractor must ensure that appropriate measures are taken to ensure the integrity of the cold chain, as well as meeting all other relevant standards throughout the Term.
- 6.10 Where vaccinations are administered to those under the age of 18 years, the Pharmacy Contractor must ensure that the relevant vaccinator has a Disclosure and Barring Service (DBS) certificate.
- 6.11 The Pharmacy Contractor must ensure appropriate processes are in place to dispose of any clinical waste, vaccine packaging and personal protective equipment (PPE) used during the vaccination process.

- 6.12 The Pharmacy Contractor is required to comply with reasonable requests from the Commissioner or waste disposal company to facilitate the safe and secure removal and safe disposal of clinical waste and PPE related to the provision of this service.
- 6.13 The Pharmacy Contractor must inform the Commissioner immediately if, for any reason, a Designated Site or any premises from which the Community Pharmacy provides the Vaccination Outreach Services and/or the administration of the vaccinations ceases to meet the criteria set out in this ES.

7. Patient eligibility

- 7.1 The Vaccination Outreach Services shall be provided in accordance with paragraph 6.2 and shall include but are not limited to:
 - 7.1.1 education and sharing resources with individuals;
 - 7.1.2 providing details on the COVID-19 vaccination and the benefits of receiving the vaccination;
 - 7.1.3 providing details on other vaccinations for which the Patient is eligible and the benefits of those vaccinations;
 - 7.1.4 signposting to other appropriate NHS services; and
 - 7.1.5 commitments set out in the Tender Response Document which is incorporated by reference as if it were annexed to this ES and are requirements as to the delivery of the Vaccination Outreach Services.
- 7.2 The Pharmacy Contractor shall only vaccinate Patients eligible to receive the vaccination by their inclusion in a JCVI Cohort which has been announced and authorised by the Commissioner as eligible for vaccination by the Pharmacy Contractor and where the following conditions are met and the administration of vaccinations:
 - 7.2.1. are provided in accordance with the Tender Response Document which is incorporated by reference as if it were annexed to this ES and are requirements as to the deivery of the administration of the vaccination;

- 7.2.2. is provided proactively by seeking Patients in the community in accordance with paragraph 6.2;
- 7.2.3. service aim is to reduce health inequalities by reaching underserved individuals and/or communities and inclusion groups;
- 7.2.4. does not include vaccination of Patients resident in care homes and/or housebound patients.
- 7.3 The Commissioner will announce the authorisation of JCVI Cohorts for vaccination by the Pharmacy Contractor.
- 7.4 The Pharmacy Contractor must make arrangements and, subject only to Patient choice must administer the COVID-19 vaccination to specified JCVI Cohorts or specified groups of Patients within a JCVI Cohort.

8. Service description

- 8.1 The Pharmacy Contractor must provide the Vaccination Outreach Services and the administration of the vaccinations in accordance with paragraphs 6.2 and 7 and must:
 - 8.1.1 ensure that vaccination is are provided in line with the Green Book, including relevant details on the treatment of anaphylaxis and secure storage and disposal of clinical waste. The Pharmacy Contractor must ensure that it has a process in place to check any updates to the Green Book;
 - 8.1.2 offer co-administration of the COVID-19 and seasonal influenza vaccinations to each Patient the Pharmacy Contractor is able to vaccinate in accordance with this ES (and the Seasonal Influenza AS) and shall only administer vaccinations to Patients who meet the requirements set out in the Green Book;
 - 8.1.3 only administer vaccinations during the Term of this ES;
 - 8.1.4 comply with the Standard Operating Procedures relating to delivery of local vaccination services and continue to meet the designation criteria as set out in the Response Document and Designation Process: and
 - 8.1.5 ensure that, where the vaccine is part of a multi-dose regimen, the Patient receives the correct dosage of the vaccine, as is clinically

appropriate, and that the Patient is advised that failure to receive all doses may render vaccination less effective. The Pharmacy Contractor should encourage the Patient to make or attend a follow up appointment to receive any subsequent dose(s).

- 8.2 The Pharmacy Contractor must follow all current guidance published by the JCVI, the Commissioner, MHRA and/or UKHSA on:
 - 8.2.1 which vaccine is the most suitable for each Patient;
 - 8.2.2 handling and manipulation of the vaccine with reference to any relevant advice and guidance from SPS²;
 - 8.2.3 the intervals between doses where multiple doses are required;
 - 8.2.4 the number of doses of each vaccine required to achieve the desired immune response; and
 - 8.2.5 any other relevant guidance relating to the administration of the different types of vaccine and the different JCVI Cohorts from time to time.
- 8.3 In the event of a conflict between guidance issued by JCVI, the Commissioner, MHRA and/or UKHSA, the Commissioner shall confirm which guidance shall be adopted.
- 8.4 Each Patient being administered a vaccination must be given written information about the vaccine as specified by UKHSA.³ A copy of the manufacturer's patient information leaflet must also be provided to the Patient (or the Patient may be directed to a web-based version of that leaflet where the Patient agrees). Where required, Patients should also be informed of any current policy as recommended by the JCVI in relation to the timing of the administration of any necessary subsequent dose where this is not reflected in the manufacturer's patient information leaflet.
- 8.5 The Pharmacy Contractor must ensure that it has in place suitable arrangements to prevent the disruption of other services or obligations of the Pharmacy Contractor under the Community Pharmacy Contractual

² https://www.sps.nhs.uk/articles/safe-practice-for-handling-multiple-covid-19-vaccines/

³ https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination

Framework, and to ensure that the consultation room remains available, when required, for patients other than those requiring vaccination.

- 8.6 Where appropriate⁴, the Pharmacy Contractor should advise the Patient about other Community Pharmacy services that are available. This could include, but is not limited to, the provision of health promotion materials, details of services and providers of those services in the local area, signposting to an online list of services in the local area and general advice and guidance. This should include signposting eligible Patients to other vaccinations, as appropriate.
- 8.7 The Pharmacy Contractor must not use provision of this ES as an opportunity to attempt to influence or seek to persuade a Patient to:
 - 8.7.1 change their choice of pharmacy;
 - 8.7.2 seek to change any prescription nominations the Patient may already have in place with other pharmacy contractors under the Community Pharmacy Contractual Framework; or
 - 8.7.3 participate in, or obtain, a Patient-funded service provided by the Pharmacy Contractor.

9. Patient access and service availability

- 9.1 The Pharmacy Contractor must ensure that the delivery of the vaccination services are accessible, appropriate and sensitive to the needs of all Patients. No Patient shall be excluded or experience particular difficulty in accessing and effectively accessing vaccination services due their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age. Patients do not require an NHS number and should not be denied COVID-19 vaccination on this basis.
- 9.2 The Pharmacy Contractor must offer COVID-19 and seasonal influenza vaccinations in accordance with paragraph 8.1.2. The Pharmacy Contractor

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⁴ The Pharmacy Contractor is reminded that pursuant to Regulation 64(3)(a) of the Pharmacy Regulations, a distance selling pharmacy must not offer to provide pharmaceutical services, other than directed services, to persons who are present at (which includes in the vicinity of) the listed chemist premises. Where this prevents the Pharmacy Contractor from advising the Patient of the matters set out in this paragraph **Error! Reference source not found.**, the Pharmacy Contractor can advise the Patient via its established non-in person procedures.

may offer COVID-19 vaccinations through the NBS and where notified by the Commissioner may offer seasonal influenza vaccinations and co-administered COVID-19 and seasonal influenza vaccinations through the NBS. This should not prevent Patients being offered each of the vaccinations where clinically appropriate and in accordance with paragraph 8.1.2.

- 9.3 Patients who have booked appointments with the NBS may ordinarily have eligibility confirmed prior to booking. The Pharmacy Contractor must confirm each Patient's eligibility prior to administration of the vaccination.
- 9.4 The Pharmacy Contractor must ensure that any Patient whose appointments are not made through the NBS are eligible for a vaccination as set out in this ES and that arrangements are made for administration of any subsequent dose(s) of a multi-dose regimen where appropriate.
- 9.5 The Pharmacy Contractor must deliver the Vaccination Outreach Services through flexible community led delivery models to improve uptake and engagement with communities as more particularly set out in their Tender Response Document. Processes must be put into place to support Patients with communication needs and/or encourage vaccination of Patients who experience other difficulties in accessing healthcare.
- 9.6 The Pharmacy Contractor may be required to operate the Vaccination Outreach Services and clinics for the administration of vaccinations to meet the needs of the local population as agreed by the Commissioner. Actual delivery hours shall be agreed with the Commissioner taking into account JCVI guidance on dosing intervals, the size of the local population eligible for vaccination and available vaccine supply, as well as the need to tailor service delivery to meet the needs of the communities set out in the Tender Response Document.
- 9.7 In the event that the Pharmacy Contractor needs to temporarily suspend the administration of vaccinations in accordance with this ES, this shall be agreed with the Commissioner and relevant changes must be made as soon as practicably possible to the NBS or relevant booking system.
- 9.8 Where there are necessary changes to planned appointments/clinics, the Pharmacy Contractor shall work with the Commissioner and shall communicate any such changes to relevant Patients.

10. Assessment and consent

- 10.1 The Pharmacy Contractor must:
 - 10.1.1 ensure that a registered healthcare professional, trained in vaccination administration and familiar with the characteristics of the vaccine being administered, assesses the Patient as eligible and suitable clinically in accordance with law and guidance prior to administering the vaccination. This assessment should include providing reasonable information that the Patient may require to make a final decision on whether to proceed with the vaccination;
 - 10.1.2 ensure that informed Patient consent is obtained by a registered healthcare professional and the Patient's consent (or refusal of consent, where relevant) to the vaccination (or the name of the person who gave (or refused) consent to the vaccination and that person's relationship to the Patient) is recorded in the Point of Care System and in accordance with law and guidance. Should the Patient decline the vaccination at any stage, this must also be recorded in the Point of Care System;
 - 10.1.3 ensure that the Patient is informed about the handling of their information in relation to the provision of this arrangement including advising the Patient that information may be anonymised and used by the Commissioner (or their agents) for the purposes of service delivery, evaluation and research; and
 - 10.1.4 comply with any relevant clinical checklists

11. Training

- 11.1 All persons involved in the provision of this ES (whether delivering the Vaccination Outreach Services or by vaccinations directly or supervising others providing vaccinations) must adhere to all relevant professional standards, regardless of the setting.
- 11.2 Vaccination Outreach Services must be provided by appropriately trained and supervised staff.

- 11.3 Vaccinations must be administered by an appropriately trained member of staff authorised under appropriate clinical supervision and using an appropriate legal mechanism.
- 11.4 All persons involved in the preparation of vaccine must be appropriately trained and have appropriate workspace to do so. This process may vary dependent upon the vaccine in use and may include dilution using standard aseptic technique and drawing up of multi-dose vials.
- 11.5 The Pharmacy Contractor must ensure that all persons involved in the administration of vaccinations have received appropriate and adequate training and are competent in the administration of those vaccinations. All persons involved in the administration of the vaccinations must:
 - 11.5.1 have completed the additional online COVID-19 specific training modules available on the e-learning for healthcare website⁵;
 - 11.5.2 have the necessary experience, skills and training⁶ including training with regard to the recognition and initial treatment of anaphylaxis;
 - 11.5.3 refer to and administer the vaccination in accordance with the most up to date version of the clinical guidance available including the relevant chapter of the Green Book; and
 - 11.5.4 be authorised by, and understand the appropriate legal mechanism for administration of the vaccination (for example, the UKHSA Patient Group Directions or National Protocols)⁷.
- 11.6 The Pharmacy Contractor must be assured to administer all COVID-19 vaccine types as required by the Commissioner.
- 11.7 The Pharmacy Contractor must ensure that it is familiar with all guidance relating to the administration, handling and storage of the different types of vaccine and that it takes steps to reduce risks associated with the handling of different vaccine types such as is outlined in any SPS guidance.

⁵ https://portal.e-lfh.org.uk/Component/Details/675208

⁶ https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators

⁷ https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanism

11.8 The Pharmacy Contractor must oversee and keep a record to confirm that all staff have undertaken the relevant training prior to participating in the administration of vaccinations. This includes any additional training associated with new vaccines that become available during the period of this ES.

12. Vaccine handling and storage

- 12.1 The Pharmacy Contractor must ensure that all vaccines are received, stored, prepared and subsequently transported (where appropriate) in accordance with the relevant manufacturer's, the UKHSA's⁸ and the Commissioner's instructions and all associated guidance set out in the 'Storage distribution and disposal of vaccines' chapter of the Green Book and all associated Standard Operating Procedures. Receipt, storage, transport and preparation of vaccines used pursuant to this ES must also be undertaken with appropriate cold chain management, clinical oversight and in accordance with governance arrangements in place for this ES.
- 12.2 The Pharmacy Contractor must ensure that any refrigerator used to store vaccine has sufficient space to store different vaccine types, with separation to reduce the risk of selection errors, and sufficient airflow to maintain effective cooling. All refrigerators in which vaccines are stored must have a thermometer that records maximum and minimum temperatures appropriate to the vaccine being administered. Readings must be recorded from that thermometer on all working days and appropriate action taken when readings are outside the recommended temperature.
- 12.3 Appropriate procedures must be in place to ensure stock rotation, monitoring of expiry dates and appropriate use of multi-dose vials to ensure that wastage is minimised and stock holdings of vaccine remain low to support the maximisation of vaccination to the population.

12.4 COVID-19 vaccines:

12.4.1 are allocated to the Pharmacy Contractor and the Pharmacy
Contractor must not share the vaccine with other providers
providing a similar vaccination service, or move the vaccine (except

⁸ UKHSA (previously PHE's) ordering, storing and handling protocol https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

- as expressly permitted by this ES), without the express prior consent of the Commissioner; and
- 12.4.2 will be supplied to the Designated Site. The Pharmacy Contractor will be responsible for the supply of consumables as may be required (for example PPE and items related to Infection Prevention and Control). The Commissioner may supply needles and syringes and will notify the Pharmacy Contractor where this is the case. The Pharmacy Contractor must be available to accept vaccine deliveries at the Designated Site according to the delivery schedule provided by the Commissioner.
- 12.5 The Pharmacy Contractor will support any national, regional and system processes in relation to COVID-19 vaccine stock forecasting and ordering arrangements, which will include complying with the processes and requirements set out in any relevant Standard Operating Procedures. This will include providing weekly updates on actual COVID-19 stock and may include, for example, providing daily or weekly updates on actual stock use, COVID-19 vaccines delivered (including the brand of COVID-19 vaccine used), COVID-19 vaccine wastage and forecasted requirements. The Pharmacy Contractor will need to submit information using a specified national system. Stock availability may be linked to the forecasted number of eligible patients locally.

13. Monitoring, reporting and record keeping

- 13.1 The Pharmacy Contractor must have signed up to receive the COVID-19 Vaccination Bulletin (or any replacement to the COVID-19 Vaccination Bulletin) by the Commencement Date and ensure it receives the COVID-19 Vaccination Bulletin published by the Commissioner so key information in relation to the delivery of this ES can be communicated in a timely manner.
- 13.2 The Pharmacy Contractor must monitor and report all activity information in accordance with the monitoring and reporting standards as published by the Commissioner and in accordance with its Terms of Service and relevant legislation. This includes guidance published by the Commissioner on the recording of COVID-19 vaccination appointments to ensure consistent national data captures. The Pharmacy Contractor must keep appropriate records of the Vaccination Outreach Services which shall be more particularly agreed with the Commissioner.

- 13.3 The Pharmacy Contractor must ensure that any staff recording the vaccination have received relevant training to be able to update records appropriately and accurately. There must be robust user and access management processes to ensure high levels of security, including frequent updates to system access levels to add users who join the site team or remove accounts where staff leave employment or do not have shifts scheduled at the site.
- 13.4 The Pharmacy Contractor must adhere to defined standards of record keeping ensuring that the vaccination event is recorded the same day that it is administered within an approved Point of Care System⁹ and that the vaccination is recorded with an 'Offsite outreach event' flag on the Point of Care system.
- 13.5 Where the Point of Care System is unavailable due to exceptional circumstances beyond the control of the Pharmacy Contractor, then the record of vaccination events must be added to the Point of Care System as soon as possible after the Point of Care System becomes available again. The Commissioner must be notified if this will result in records of vaccination being added to the Point of Care System on a different day than the vaccinations were administered. Where the record of the vaccination event is not created within 15 days of the vaccination being administered, the Pharmacy Contractor shall not be eligible for the item of service fees and any associated additional payments as set out at paragraph 15. Where the item of service fee and/or any additional payments are claimed and/or automatically submitted payments shall be recoverable by the Commissioner in accordance with paragraph 15.11.
- 13.6 Where a record of the vaccination needs to be amended or has not been created on the Point of Care system, the Pharmacy Contractor is responsible for undertaking the amendment or creation as soon as reasonably possible following notification that the record contains an error.
- 13.7 The Commissioner will provide access to an online Point of Care System for making records of vaccinations.
- 13.8 The Pharmacy Contractor:

⁹ https://digital.nhs.uk/services/vaccinations-point-of-care

- 13.8.1 must only enter new vaccinations into a single Point of Care System in any calendar month except:
 - 13.8.1.1 during the transition to a new Point of Care System where the use of two systems will be permitted for a period determined by the Commissioner; or
 - 13.8.1.2 subject to paragraph 13.6, where it is necessary to include amendments to vaccination events previously recorded; and
- 13.8.2 is responsible for ensuring that the quality and connectivity of access to the Point of Care System is sufficient to ensure the timely recording of vaccinations and to support sufficient access to the Point of Care System in accordance with this paragraph 13.
- 13.9 The Pharmacy Contractor is responsible for recording adverse events and providing the Patient with information on the process to follow if they experience an adverse event in the future after leaving the vaccination site, including signposting the Yellow Card service.
- 13.10 The Pharmacy Contractor is expected to follow the UKHSA: <u>"Vaccine incident guidance"</u>, responding to errors in vaccine storage, handling and administration.
- 13.11 The Pharmacy Contractor must maintain appropriate records to ensure effective ongoing delivery and governance. Records must be managed in line with 'Records Management Code of Practice for Health and Social Care'. 10

14. Governance and accountability

14.1 The Responsible Pharmacist at the registered pharmacy premises is professionally responsible for the safe delivery of this ES at the Designated Site. If the Responsible Pharmacist is unable to provide sufficient supervision of the ES, for example due to workload or where the Designated Site is located in a location other than the main pharmacy premises, an on-site pharmacist(s) supervising the Designated Site must be linked and work closely with the Responsible Pharmacist and

¹⁰ https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-and-social-care

Superintendent Pharmacist through an appropriate governance framework. This on-site supervising pharmacist must be registered with the GPhC and trained in vaccinations, including a clear understanding of this ES. A record must be maintained of who that person is at each site at all times and made available to the Commissioner on request.

- 14.2 The Pharmacy Contractor must ensure that it has in place appropriate indemnity and/or insurance arrangements that provide adequate cover, including but not limited to clinical negligence cover, in relation to the delivery of this ES, and that the indemnity and/or insurance arrangements provide such cover for all clinical professionals and other staff working in connection with the delivery of the services pursuant to the ES, including where vaccinations are administered in locations other than the pharmacy premises.
- 14.3 Where a Patient experiences an adverse drug reaction or presents with an adverse drug reaction following the vaccination and the Pharmacy Contractor believes this is of clinical significance, such that the Patient's general practice should be informed, this information should be shared with the general practice as soon as possible, and a 'Yellow Card'¹¹ report submitted.

15. Payment arrangements¹²

- 15.1. Subject to paragraph 15.3, from the Expected COVID-19 Vaccination Administration Commencement Date to 31 March 2026 and subject to compliance with this ES, the Commissioner will pay:
 - 15.1.1. an item of service payment of £7.54 to the Pharmacy Contractor for administration of each COVID-19 vaccination to each Patient; and
 - 15.1.2. where the Commissioner notifies the Pharmacy Contractor in advance (including the timeframe to which this £2.50 payment shall apply), the Commissioner will pay £2.50 to the Pharmacy Contractor for the administration of each COVID-19 vaccination to each Patient where the seasonal influenza vaccination is not

¹¹ https://yellowcard.mhra.gov.uk/

¹² For further information on payments please see the Community Pharmacy Finance and Payments Guidance available here: https://future.nhs.uk/vaccsandscreening/view?objectID=38665872

announced and authorised for vaccination by the Pharmacy Contractor; and

- 15.2. From the Vaccination Outreach Services Commencement Date to 31 March 2026 and subject to compliance with this ES, the Commissioner will pay:
 - 15.2.1. [insert] to the Pharmacy Contractor for the Vaccination Outreach Services.
- 15.3. The Commissioner will pay the sums as set out at paragraph 15.1 and 15.2 unless the Commissioner notifies the Pharmacy Contractor of a change to the payment sums on at least 49 days notice.
- 15.4. Claims for payments for this ES set out in paragraph 15.1 must be made via the Manage Your Service (MYS) portal provided by the NHS Business Services Authority (the NHSBSA). Claims should be made by the 5th day of the month following the month in which administration of the vaccination occurred (the "Expected Claim Date") but will be accepted by the NHSBSA if they are submitted within three months of the Expected Claim Date. Any claims that are submitted later than three months following the Expected Claim Date will not be processed and the Pharmacy Contractor will not receive any item of service payment for those vaccinations.
- 15.5. Claims for payments for this ES set out in paragraph 15.2 shall be paid in accordance with the method agreed in writing with the Commissioner.
- 15.6. Claims for payments for this ES set out in paragraph 15.1 will only be paid where Vaccination Outreach Services have been provided and:
 - 15.6.1. the Patient in respect of whom payment is being claimed was within one of the eligible JCVI Cohorts and that JCVI Cohort was announced and authorised by the Commissioner for the administration of the vaccination by the Pharmacy Contractor at the time the vaccination was administered;
 - 15.6.2. the Pharmacy Contractor has used a COVID-19 vaccine supplied and recommended in accordance with the latest advice;
 - 15.6.3. the administration of the vaccination has been recorded on the specified Point of Care System on the day of the administration of the vaccination to the Patient and has been recorded with an

'Offsite outreach event' flag on the Point of Care system. In exceptional circumstances, where it has not been possible to record the vaccination event on the day of the administration of the vaccination, and the Pharmacy Contractor has recorded the exceptional circumstances on the Point of Care system as soon as possible afterwards and within 15 days of the day on which the vaccination was administered, the Pharmacy Contractor will be eligible for the item of service fees and any associated additional payments. Where the record of the vaccination event is not created within 15 days of the vaccination being administered, the Pharmacy Contractor shall not be eligible for the item of service fees and any associated additional payments;

- 15.6.4. the Pharmacy Contractor has not received and does not expect to receive any payment from any other source (other than any discretionary funding made available by the Commissioner relating to the delivery of the COVID-19 vaccination programme) in respect of the vaccine or vaccination event; and
- 15.6.5. the claim for payment was submitted in accordance with paragraph **Error! Reference source not found.**3.
- 15.7. If the Pharmacy Contractor does not satisfy all relevant provisions of this ES, the Commissioner may determine to withhold payment of all, or any part of, an amount due under this ES that is otherwise payable.
- 15.8. The Pharmacy Contractor must comply with any reasonable requests to facilitate post payment verification. This may include auditing claims to ensure that it meets the requirements of this ES.
- 15.9. Payment under this ES, or any part thereof, is conditional on the Pharmacy Contractor satisfying the following:
 - 15.9.1. entering into this ES, including any variations and updates;
 - 15.9.2. complying (and maintaining compliance) with the requirements of this ES;
 - 15.9.3. making available to the Commissioner any information under this ES which the Commissioner needs and the Pharmacy Contractor either has or could be reasonably expected to obtain;

- 15.9.4. making any returns (including payment claims as required by this paragraph 15) or providing any information reasonably required by the Commissioner (or on the Commissioner's behalf) (whether computerised or otherwise) to support payment and do so promptly and fully; and
- 15.9.5. ensuring that all information supplied pursuant to or in accordance with this paragraph 15 is accurate.
- 15.10. The Pharmacy Contractor may not claim payment for Patients vaccinated by any other provider (for example, at a vaccination centre operated by another provider).
- 15.11. If the Commissioner makes a payment to a Pharmacy Contractor under this ES and:
 - 15.11.1. the Pharmacy Contractor was not entitled to receive all or part thereof, whether because it did not meet the entitlement conditions for the payment or because the payment was calculated incorrectly (including where a payment on account overestimates the amount that is to fall due);
 - 15.11.2. the Commissioner was entitled to withhold all or part of the payment because of a breach of a condition attached to the payment, but is unable to do so because the money has already been paid; or
 - 15.11.3. the Commissioner is entitled to repayment of all or part of the money paid,

the Pharmacy Contractor agrees that the Commissioner may recover the money paid by deducting an equivalent amount from any payment payable to the Pharmacy Contractor, and where no such deduction can be made, it is a condition of the payments made under this ES that the Pharmacy Contractor must pay to the Commissioner that equivalent amount.

16. Variations to and subsequent withdrawal from this ES

16.1 Variations to this ES will be published on https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/

- and will take effect immediately on publication. The Pharmacy Contractor will also be notified of any changes by the Commissioner.
- 16.2 In order to simplify the process, where there are any variations to this ES after the Pharmacy Contractor's submission of its Tender Response Document, the Pharmacy Contractor which has confirmed its agreement to enter into this ES will be deemed to agree to the variations, unless the Pharmacy Contractor notifies the Commissioner in accordance with paragraph 16.3.
- 16.3 If the Pharmacy Contractor cannot meet the revised requirements of this ES it must withdraw from this ES by serving written notice on the Commissioner to that effect with supporting reasons as to why it cannot meet the revised requirements, such notice must be received by the Commissioner no later than 42 days after publication of the relevant variation and providing no less than 42 days' written notice of the Pharmacy Contractor's withdrawal.