

# Community Pharmacy Enhanced Service COVID-19 vaccination programme: 1 September 2024 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 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 September 2024
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 Enhanced Service: COVID-19 Vaccination programme: 1 September 2024 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
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- 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.

<b>Signed for and on behalf of the Commissioner:</b>	<b>Signed for and on behalf of the Pharmacy Contractor:</b>
Signature .....	Signature .....
Name .....	Name .....
Job title .....	Job title .....
Date .....	Date .....

## 1. Introduction

- 1.1 The Pharmacy Contractor has submitted a Response Document and has been awarded this arrangement to provide services in accordance with this Enhanced Service (ES<sup>1</sup>). 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 has been developed from earlier phases of the COVID-19 vaccination programme. It is a national specification that cannot be varied locally.
- 1.3 This ES is a 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 clinical care, 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 An aim of this ES is to maximise the uptake and co-administration of COVID-19 and seasonal influenza vaccinations where possible and to ensure that vaccination services are provided from a variety of settings and effectively utilise available staff from across primary care.

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<sup>1</sup> 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 agreement cannot 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 **“Care Home”** means specific types of care homes which shall be announced and authorised by the Commissioner;
  - 2.2.2 **“Commencement Date”** means 1 September 2024;
  - 2.2.3 **“Commissioner”** means NHS England;
  - 2.2.4 **“CQC”** means the Care Quality Commission;
  - 2.2.5 **“Designated Site”** means the premises nominated by a Pharmacy Contractor and approved by the Commissioner in accordance with the Designation Process as the premises from which the vaccination will be administered to Patients unless otherwise in accordance with this ES or agreed by the Commissioner;
  - 2.2.6 **“Designation Process”** means the COVID-19 Assurance and Site Designation process set out in the COVID-19 Vaccination Site Signup Process Guidance 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;
  - 2.2.7 **“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;
  - 2.2.8 **“Expected 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. Where the date announced by the Commissioner is no less than 4 weeks following the Commencement Date, the administration of vaccinations shall commence from the date announced by the Commissioner. Where the date announced by the Commissioner is less than 4 weeks following the Commencement Date, the administration of vaccinations shall commence on a date to be

agreed with the Commissioner. Where the Commencement Date is later than the date announced by the Commissioner the administration of vaccinations shall commence from the Commencement Date;

- 2.2.9 “**GPhC**” means the General Pharmaceutical Council;
- 2.2.10 “**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> ;
- 2.2.11 “**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 as set out at paragraph 3.6;



- 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 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 **“Response Document”** means the response to the COVID-19 Vaccination Site Signup Process Guidance whereby the Pharmacy Contractor is awarded this arrangement to deliver services under this ES;
- 2.2.25 **"Seasonal Influenza AS"** means each of the Seasonal Influenza Vaccination Programme Advanced Service Specifications for 2024/25 and 2025/26 which are capable of being entered into by the Pharmacy Contractor during the Term;
- 2.2.26 **"Short Term/Temporary Site"** means a clinically appropriate short-term or temporary clinic run by the Pharmacy Contractor to administer vaccinations (for example, a one-off clinic, a clinic running for a week, a clinic running twice a week for two weeks). This may be at or away from the Designated Site. The vaccine may only be stored overnight at GPhC/CQC registered premises, in accordance with approved medicines management arrangements and the Pharmacy Contractor will use vaccine and any related consumables and systems supplied to the Designated Site;

- 2.2.27 "**Site Capacity**" means at least 100 COVID-19 vaccinations per week which the Pharmacy Contractor has offered to provide (and which will not otherwise impact its delivery of pharmaceutical services) in its Response Document and has been agreed by the Commissioner to be administered during each week of the Term, subject to Patient demand;
- 2.2.28 "**SPS**" means the Specialist Pharmacy Service;
- 2.2.29 "**Surge**" means an operational response for the management of a rapid, short-term increase in capacity as a consequence of a new variant or a specific instruction to vaccinate or revaccinate a defined population. It is a system change in line with JCVI Guidance to ensure the defined population in England is offered and has access to a COVID-19 vaccination;
- 2.2.30 "**Term**" means the period from the Expected Service Commencement Date to the End Date;
- 2.2.31 "**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; and
- 2.2.32 "**UKHSA**" means the UK Health Security Agency.

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, extend the Term by up to 12 months.

- 3.3 The administration of vaccinations shall commence with effect from the Expected Service Commencement Date.
- 3.4 Where the Pharmacy Contractor is unable to commence the administration of vaccinations within 4 weeks of the Expected Service Commencement Date, the Pharmacy Contractor must notify the Commissioner as soon as reasonably possible.
- 3.5 The Commissioner may agree with the Pharmacy Contractor an extension not exceeding 8 weeks following the Expected Service Commencement Date to commence the administration of vaccinations. Failure to begin the administration of vaccinations within the agreed timeframe will result in termination of the ES on a date to be notified by the Commissioner to the Pharmacy Contractor.
- 3.6 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 and/or the Designated Site does not represent acceptable value for money to the Commissioner, the Commissioner may require the Pharmacy Contractor to suspend the COVID-19 vaccination services (a “**Pause**”).
- 3.7 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 and/or the Designated Site represents acceptable value for money to the Commissioner and the Commissioner shall, acting reasonably, reconsider whether it remains appropriate to continue with the Pause.
- 3.8 During a Pause, the Pharmacy Contractor shall not administer COVID-19 vaccinations 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.
- 3.9 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 vaccination and should direct Patients to available services, as appropriate.

- 3.10 Where there is, in the reasonable view of the Commissioner, a requirement to increase capacity at pace (Surge), the Pharmacy Contractor shall agree with the Commissioner its role in the system wide response to the Surge, both in terms of increased volume and rapid timeframe for the administration of COVID-19 vaccinations.
- 3.11 It is a condition of this ES that the Pharmacy Contractor must also deliver each Seasonal Influenza AS during the Term. The offer of co-administration of the COVID-19 and seasonal influenza vaccinations, subject to vaccine availability, must be made to each 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 comes to an end (and which shall be announced by the Commissioner);
  - 3.12.2 automatically where the Pharmacy Contractor has not provided vaccinations under the Seasonal Influenza AS for the preceding 56 days or otherwise agreed by the Commissioner and save for in exceptional circumstances or where the seasonal influenza vaccination programme has come to an end before the COVID-19 vaccination programme;
  - 3.12.3 automatically on the same date as a decision of the Pharmacy Contractor to permanently cease to provide the Seasonal Influenza AS;
  - 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;

3.12.7 immediately or on such notice as the Commissioner deems appropriate where the Pharmacy Contractor is unable to meet the Site Capacity; or

3.12.8 immediately where the Pharmacy Contractor does not commence the administration of vaccinations in accordance with paragraph 3.3 to 3.5.

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/>.

3.14 On termination of this ES, the Pharmacy Contractor shall work with the Commissioner and any providers commissioned by the Commissioner for the delivery of any subsequent doses of COVID-19 vaccination to Patients.

## 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 will have the ability to administer the Site Capacity (subject to the vaccine supply). 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 and support the high uptake of vaccinations.

## 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 administration 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 Response Document.

- 6.2 The Commissioner will approve the Designated Site in accordance with the Response Document and the Designation Process.
- 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.
- 6.4 Any amendments, additions or the removal of the Designated Site shall only be permitted with the agreement of the Commissioner.
- 6.5 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 to undertake an assessment of the readiness of the Designated Site 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 Vaccinations administered in accordance with this ES must be administered at the Designated Site unless;
- a. required by the Commissioner in accordance with paragraph 6.10; or
  - b. the Pharmacy Contractor notifies the Commissioner (by reasonable notice and in advance) that it intends to deliver a Short Term/Temporary Site for the administration of vaccinations and to improve vaccination uptake on given date(s) and/or time(s) to permit vaccination of specific Patient groups).
  - c. The majority of vaccinations must take place at the Designated Site.
- 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. Vaccinations must take place in a consultation room whenever the patient expresses this preference.

- 6.9 Where a Patient is unable to access the Designated Site and the Commissioner (acting reasonably) requires the Pharmacy Contractor to make arrangements to vaccinate patients in other suitable locations, such as (but not limited to) in the Patient's home, a Care Home, or a residential facility, the Pharmacy Contractor must make these arrangements within 8 weeks of the Commissioner requirement being communicated to the Pharmacy Contractor, or as soon as reasonably possible, as agreed in advance with the Commissioner. The delivery of vaccinations in accordance with this paragraph 6.10 is not Short Term/Temporary Site activity, which must be notified to the Commissioner in accordance with paragraph 6.7.2.
- 6.10 Where vaccinations are administered at locations other than the Designated Site in accordance with paragraph 6.7 and/or paragraph 6.10, the Pharmacy Contractor must continue to ensure that appropriate measures are taken to ensure the integrity of the cold chain, as well as meeting all other relevant standards.
- 6.11 Where vaccinations are administered to those under the age of 18 years and/or undertaken in the Patient's own home (including a care home), the Pharmacy Contractor must ensure that the relevant vaccinator has a Disclosure and Barring Service (DBS) certificate.
- 6.12 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.
- 6.13 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 (including where the vaccination is undertaken off the pharmacy premises).
- 6.14 The Pharmacy Contractor must inform the Commissioner immediately if, for any reason, a Designated Site ceases to meet the criteria set out in this ES.



## 7. Patient eligibility

- 7.1 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.
- 7.2 The Commissioner will announce the authorisation of JCVI Cohorts for vaccination by the Pharmacy Contractor.
- 7.3 The Pharmacy Contractor must administer the vaccinations to Patients in the priority order announced and authorised by the Commissioner.
  - d. The Pharmacy Contractor acknowledges that the authorisation of and priority order of JCVI Cohorts will change throughout the Term and must ensure that it complies with the announcements, authorisations and priority orders in place at the date of the administration of vaccinations, throughout the Term.

## 8. Service description

- 8.1 The Pharmacy Contractor must:
  - 8.1.1 ensure that vaccinations 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. Where it is operationally expedient and clinically appropriate co-administration of other vaccinations commissioned from the Pharmacy Contractor should be provided if possible;
  - 8.1.3 only administer vaccinations during the Term of this ES;

- 8.1.4 comply with any relevant guidance and Standard Operating Procedures for managing COVID-19 vaccinations (as updated from time to time) and continue to meet the designation criteria as set out in the Response Document and Designation Process;
  - 8.1.5 only administer vaccinations to Patients aged 18 years or over unless or until the provisions at paragraph 10.1.4 have been complied with and the Commissioner has indicated in writing that the Pharmacy Contractor may vaccinate those aged under 18 years of age;
  - 8.1.6 identify people eligible for COVID-19 vaccination who present at the pharmacy and encourage them to be vaccinated; and
  - 8.1.7 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 SPS<sup>2</sup>;
  - 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.

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

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- 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.<sup>3</sup> 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 Framework, and to ensure that the consultation room remains available, when required, for patients other than those requiring vaccination.
- 8.6 Where appropriate<sup>4</sup>, the Pharmacy Contractor should advise the Patient attending for vaccination at the Designated Site 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;

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

<sup>4</sup> 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 4.5, the Pharmacy Contractor can advise the Patient via its established non-in person procedures.

- 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 must 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. It must comply with the requirements of the NBS, including in ensuring that accurate information is published and in uploading appointment / clinic times in a timely way to allow Patient bookings to take place.
- 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 is strongly encouraged to offer vaccinations through advertised walk-in clinics or alternative arrangements to improve uptake or engagement with communities as agreed with the Commissioner.

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 regular clinics in the evenings, at weekends and on bank holidays to meet the needs of the local population as agreed by the Commissioner. Actual delivery hours shall be agreed with the Commissioner having regard to the Site Capacity, JCVI guidance on dosing intervals, the size of the local population eligible for vaccination and available vaccine supply.
- 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.
- 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 to the vaccination (or the name of the person who gave 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 (which will include the sharing that will take place for the appropriate recording of the vaccination in their general practice record) 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 (including checklists relevant to the vaccination of those under 18 years of age).
- 10.2 Where a Patient is aged under 18 years, the Pharmacy Contractor may administer vaccinations where the following has been satisfied:
- 10.2.1 the Pharmacy Contractor has complied with the provisions at paragraph 10.1.4;
  - 10.2.2 the Commissioner has confirmed in writing that the Pharmacy Contractor may administer vaccinations to Patients of the relevant age group; and
  - 10.2.3 the Patient has been assessed as competent to consent and does consent, or the Patient is not assessed as competent but does not object and consent is provided by somebody with parental responsibility.

## 11. Training

- 11.1 All persons involved in the provision of this ES (whether delivering vaccinations directly or supervising others providing vaccinations) must adhere to all relevant professional standards, regardless of the setting.
- 11.2 Vaccinations must be administered by an appropriately trained member of staff authorised under an appropriate legal mechanism (for example the UKHSA Patient Group Directions or National Protocols<sup>5</sup>).
- 11.3 All persons involved in the preparation of vaccines must be appropriately trained and have appropriate workspace to do so. This process may vary

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<sup>5</sup> <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanisms/>

dependent upon the vaccine in use and may include dilution using standard aseptic technique and drawing up of multi-dose vials.

- 11.4 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:
- 11.4.1 have completed the additional online COVID-19 specific training modules available on the e-learning for healthcare website<sup>6</sup>;
  - 11.4.2 have the necessary experience, skills and training<sup>7</sup> including training with regard to the recognition and initial treatment of anaphylaxis;
  - 11.4.3 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
  - 11.4.4 be authorised by, and understand the appropriate legal mechanism for administration of the vaccination (for example, the UKHSA Patient Group Directions or National Protocols)<sup>8</sup>.
- 11.5 The Pharmacy Contractor must be assured to administer all COVID-19 vaccine types as required by the Commissioner.
- 11.6 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.
- 11.7 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.

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<sup>6</sup> <https://portal.e-lfh.org.uk/Component/Details/675208>

<sup>7</sup> <https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators>

<sup>8</sup> <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanism>

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## 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's<sup>9</sup> 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 vaccinations 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 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).

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<sup>9</sup> UKHSA (previously PHE's) ordering, storing and handling protocol  
<https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>

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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.
- 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 System<sup>10</sup>.
- 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 vaccinations 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 15.9.
- 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:
- 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

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<sup>10</sup> <https://digital.nhs.uk/services/vaccinations-point-of-care/community-pharmacy>

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 internet broadband at the Designated Site is sufficient to support access to the Point of Care System during the hours of operation or as agreed with the Commissioner.

13.9 The Pharmacy Contractor must comply with any reasonable request for information from the Commissioner relating to the provision of services under this arrangement.

13.10 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.

13.11 The Pharmacy Contractor is expected to follow the UKHSA: "[Vaccine incident guidance](#)", responding to errors in vaccine storage, handling and administration.

13.12 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'.<sup>11</sup>

## 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 Superintendent Pharmacist through an appropriate governance framework. This on-site supervising pharmacist must be registered with the GPhC and trained in vaccinations,

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<sup>11</sup> <https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-and-social-care>

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'<sup>12</sup> report submitted.

## 15. Payment arrangements<sup>13</sup>

- 15.1. From the Expected Service Commencement Date to 31 March 2025 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 the administration of each COVID-19 vaccination to each Patient;
  - 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 announced and authorised for vaccination by the Pharmacy Contractor; and
  - 15.1.3. £10.00 to the Pharmacy Contractor for administration of each COVID-19 vaccination to each Patient where:

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<sup>12</sup> <https://yellowcard.mhra.gov.uk/>

<sup>13</sup> For further information on payments please see the Community Pharmacy Finance and Payments Guidance available here: <https://future.nhs.uk/CovidVaccinations>

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15.1.3.1. the Pharmacy Contractor is advised by the Commissioner or the Patient's general practice that the medical condition of a Patient is such that, the Patient is classed as housebound due to being unable to leave their home at all or requires significant assistance to leave the house due to illness, frailty, surgery, mental ill health or nearing end of life and is recorded as such in their clinical notes;

15.1.3.2. that Patient requires administration of a vaccination which has been agreed by the Commissioner to be undertaken by the Pharmacy Contractor;

15.1.3.3. the Pharmacy Contractor has recorded the status of the Patient in the Point of Care System prior to making the claim for payment; and

15.1.3.4. that Patient has been offered co-administration of a seasonal influenza vaccination where the Patient is eligible for a seasonal influenza vaccination; and

which for the avoidance of doubt, excludes Patients resident in Care Homes.

15.2. From 1 April 2025 and subject to continued compliance with this ES the Commissioner will pay the sums as set out at paragraph 15.1 unless the Commissioner notifies the Pharmacy Contractor of a change to the payment sums from 1 April 2025 at least 49 days prior to 1 April 2025.

15.3. Claims for payments for this ES set out in paragraph 15.1 and 15.2 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 5<sup>th</sup> 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.

15.4. Claims submitted in accordance with this ES will only be paid where:

- 15.4.1. 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;
  - 15.4.2. the Pharmacy Contractor has used a COVID-19 vaccine supplied and recommended in accordance with the latest advice;
  - 15.4.3. 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. 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;
  - 15.4.4. 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; and
  - 15.4.5. the claim for payment was submitted in accordance with paragraph 15.3.
- 15.5. 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.
  - 15.6. 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.

- 15.7. Payment under this ES, or any part thereof, is conditional on the Pharmacy Contractor satisfying the following:
  - 15.7.1. entering into this ES, including any variations and updates;
  - 15.7.2. complying (and maintaining compliance) with the requirements of this ES;
  - 15.7.3. 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;
  - 15.7.4. 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
  - 15.7.5. ensuring that all information supplied pursuant to or in accordance with this paragraph 15 is accurate.
- 15.8. The Pharmacy Contractor may not claim payment for Patients vaccinated by any other provider (for example, at a vaccination centre operated by another provider).
- 15.9. If the Commissioner makes a payment to a Pharmacy Contractor under this ES and:
  - 15.9.1. 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);
  - 15.9.2. 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
  - 15.9.3. 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.

- 15.10. The Commissioner may, at its discretion for example, in the event of a Surge, make additional payments to the Pharmacy Contractor to support the administration of vaccinations in exceptional circumstances.

## **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 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.