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Community Pharmacy Enhanced Service

COVID-19 vaccination programme: 1 September 2023 to 31 March 2024

This document is the COVID-19 vaccination enhanced service specification for community pharmacy for the 2023/24 COVID-19 vaccination programme.

Version 1, 4 August 2023

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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Introduction

This document sets out the detail of how NHS England will commission a Covid-19 vaccination service directly from community pharmacy. It is commissioned where there is a requirement for Covid-19 vaccinations and where Pharmacy Contractors can meet the minimum requirements from their pharmacy premises, or where there is a local population need and where NHS England considers the Pharmacy Contractor is best placed to meet that need via provision at off-site premises. The service will be provided as an Enhanced Service ("an ES"), commissioned by NHS England in consultation with Community Pharmacy England.

The aim of this service 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 across primary care.

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.

This ES is subject to amendments from time to time as the COVID-19 vaccination programme develops.

This ES has been developed from earlier phases of the COVID-19 vaccination programme following feedback from pharmacy contractors and citizens. It is a national specification that cannot be varied locally.

This ES relates to the period from 1 September 2023 to 31 March 2024 for Covid-19 vaccinations only.

1 Agreement between the parties

- 1.1 The Commissioner commissions the Pharmacy Contractor to provide Covid-19 vaccinations to Patients in accordance with this ES.
- 1.2 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.
- 1.3 The Pharmacy Contractor shall provide the service in accordance with the terms of this ES and in full compliance with their Terms of Service or Local Pharmaceutical Services contract terms, as applicable to the Pharmacy Contractor.

Commencement Date	[[1] September 2023]
Commissioner	NHS England
	Address for service of notice:
	[Insert]
Pharmacy Contractor	[Insert Pharmacy Contractor's names (as set out in the relevant pharmaceutical list) and address]
National Enhanced Service (ES)	Community pharmacy enhanced service: COVID-19 Vaccination programme: 1 September 2023 to 31 March 2024
Designated Site	[insert address of the Designated Site]
Service Payment	Means the payment set out at paragraph Error! Reference source not found

Site Capacity	[<i>Insert number of vaccinations per week</i>] means the number of vaccinations per week that the pharmacy contractor is prepared to administer and has agreed with the Commissioner, subject to vaccine supply.	
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 and which the Commissioner has announced and authorised as at the Commencement Date and which is subject to amendment by notification from the Commissioner to the Pharmacy Contractor.	

- 1.4 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.
- 1.5 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 Commissioner:	Signed for and on behalf of the Pharmacy Contractor:
Signature	Signature
Name	Name
Job title	Job title
Date	Date

2 Definitions

- 2.1 This specification is referred to as this "ES".
- 2.2 In this ES:
 - 2.2.1 **"Care Home"** refers to specific types of care homes which shall be announced and authorised by the Commissioner;
 - 2.2.2 **"Commissioner"** means NHS England (previously the National Health Service Commissioning Board, known as NHS England);
 - 2.2.3 **"Designated Site"** refers to a site nominated by a Pharmacy Contractor and approved by the Commissioner as the premises from which the vaccination will be administered to Patients (unless otherwise approved by the Commissioner) and as further described in this ES;
 - 2.2.4 "End Date" means 31 March 2024 unless terminated earlier in accordance with paragraph 3.5 or otherwise in accordance with this ES;
 - 2.2.5 "Expression of Interest Process" refers to the process whereby the Pharmacy Contractor is selected to deliver services under this ES;
 - 2.2.6 "GPhC" means the General Pharmaceutical Council;
 - 2.2.7 "Green Book" means the green book, 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
 - 2.2.8 "JCVI" means the Joint Committee on Vaccination and Immunisation;

- 2.2.9 "JCVI Cohorts" are the cohorts of Patients referenced following JCVI advice;
- 2.2.10 **"MHRA"** means the Medicines and Healthcare products Regulatory Agency;
- 2.2.11 **"Ministerial Decision"** means a decision issued by the Secretary of State for Health and Social Care;
- 2.2.12 "**National Booking Service (NBS)**" means the service linked to the call/recall services and used by Patients to book Covid-19 vaccination appointments;
- 2.2.13 **"NHS Digital**" means the part of NHS England which was previously the Health and Social Care Information Centre;
- 2.2.14 **"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;
- 2.2.15 **"Pause**" means a pause to the requirement for the administration of Covid-19 vaccinations as set out at paragraph 3.4;
- 2.2.16 "Pharmaceutical List" means the pharmaceutical list prepared, maintained and published by NHS England pursuant to regulation 10(2)(a) of the Pharmacy Regulations;
- 2.2.17 "Pharmaceutical Services" has the meaning set out in the Pharmacy Regulations;
- 2.2.18 "Pharmacy Regulations" means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended;
- 2.2.19 "**Point of Care System**" means a clinical system that has been assured by NHS Digital to record Covid-19 vaccination events;
- 2.2.20 "Service Commencement Date" means the date established in accordance with paragraph 3.2;

- 2.2.21 "SPS" means Specialist Pharmacy Service;
- 2.2.22 **"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;
- 2.2.23 **"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;
- 2.2.24 "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 3.5.
- 3.2 Subject to paragraph 3.3, the Service Commencement Date shall be announced in the Primary Care Bulletin.
- 3.3 Where the Commencement Date is less than 4 weeks before the Service Commencement Date announced in the Primary Care Bulletin, the Service Commencement Date shall be agreed with the Commissioner.
- 3.4 In relation to fluctuations in the requirement for Covid-19 vaccinations:
 - 3.4.1 where there is (in the reasonable view of the Commissioner) significantly reduced Patient demand, there is unacceptable wastage of the 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 vaccination services (a "Pause").

- 3.4.2 where the Pharmacy Contractor does not agree to the Pause, they may provide evidence to the Commissioner detailing that there is no significantly reduced Patient demand, there is not unacceptable wastage of the 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.
- 3.4.3 during a Pause, the Pharmacy Contractor shall not administer Covid-19 vaccinations and shall not be entitled to claim or receive any payment 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.
- 3.4.4 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.
- 3.4.5 where there is, in the reasonable view of the Commissioner, a requirement to increase capacity at pace to respond to a Surge, the Pharmacy Contractor shall agree with the Commissioner their role in the system wide response to the Surge, both in terms of increased volume and rapid timeframe.
- 3.5 This ES may be terminated on any of the following events:
 - 3.5.1 automatically when the COVID-19 vaccination programme comes to an end;
 - 3.5.2 by the Commissioner providing not less than 42 days' notice to the Pharmacy Contractor;

- 3.5.3 by the Pharmacy Contractor providing not less than 42 days' notice to the Commissioner, unless otherwise agreed with the Commissioner;
- 3.5.4 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;
- 3.5.5 immediately or on such notice as the Commissioner deems appropriate where the Pharmacy Contractor is unable to meet the requirements of this ES in accordance with paragraph 14.5; or
- 3.5.6 where the Pharmacy Contractor does not commence the administration of vaccinations in accordance with paragraphs 4.3 and 4.4.

4 Service description

- 4.1 The Pharmacy Contractor must comply with the SPS Standard Operating Procedures relating to delivery of local vaccination services in community settings (as updated from time to time) and continue to meet the designation criteria as set out in the Expression of Interest Process.
- 4.2 Subject to paragraph 9.2.4, the Pharmacy Contractor may administer vaccinations in accordance with this ES from the Service Commencement Date. The Pharmacy Contractor must commence the administration of vaccinations within 4 weeks of the Service Commencement Date. The Pharmacy Contractor must contact the Commissioner as soon as reasonably possible in the event that they are unable to begin vaccination within 4 weeks of the Service Commencement Date.
- 4.3 The Commissioner may agree with the Pharmacy Contractor an extension not exceeding a further 4 weeks to commence the administration of vaccinations. Failure to begin the administration of vaccinations within these timeframes will result in termination of the ES on a date to be notified by the Commissioner to the Pharmacy Contractor.

- 4.4 The Pharmacy Contractor must also deliver the Community Pharmacy Seasonal Influenza Vaccination Advanced Service. The offer of coadministration of the Covid-19 and seasonal influenza vaccines, subject to vaccine availability, must be made to each Patient the Pharmacy Contractor is able to vaccinate in accordance with the Community Pharmacy Seasonal Influenza Advanced Service, this ES and recommendations for coadministration in the Green Book.
- 4.5 Where it is operationally expedient, co-administration of other vaccinations commissioned from the Pharmacy Contractor should be provided if possible.
- 4.6 Where appropriate¹, Pharmacy Contractors 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.
- 4.7 The Pharmacy Contractor must not use provision of this ES as an opportunity to attempt to influence or seek to persuade a Patient to:
 - 4.7.1 change their choice of pharmacy;
 - 4.7.2 seek to change any prescription nominations the Patient may already have in place with other Pharmacy Contractors under the Community Pharmacy Contractual Framework; or
 - 4.7.3 participate in, or obtain, a Patient-funded service provided by the Pharmacy Contractor.

5 Patient eligibility

5.1 The Pharmacy Contractor may vaccinate Patients eligible to receive the vaccination by their inclusion in a JCVI Cohort which has been announced

¹ 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.

and authorised by the Commissioner as eligible for vaccination by the Pharmacy Contractor.

- 5.2 The Commissioner will announce the authorisation of JCVI Cohorts for vaccination by Pharmacy Contractors using the Primary Care Bulletin and/or the Vaccination Site Bulletin.
- 5.3 The Pharmacy Contractor must administer the vaccinations to Patients in the priority order announced and authorised by the Commissioner.
- 5.4 The Pharmacy Contractor must:
 - 5.4.1 not deny a vaccination to any patient on the basis that they do not have an NHS number or GP registration;
 - 5.4.2 only administer Covid-19 vaccinations to Patients who meet the requirements set out in the Green Book;
 - 5.4.3 only administer vaccinations to Patients aged 18 years or over unless or until the provisions at paragraph 7.1 have been complied with and the Commissioner has indicated in writing that the Pharmacy Contractor may vaccinate those aged under 18 years of age; and
 - 5.4.4 identify people eligible for Covid-19 vaccination who present at the pharmacy and encourage them to be vaccinated.
- 5.5 Patients who have booked appointments with the NBS will ordinarily have eligibility confirmed prior to booking. Any additional checks on eligibility that Pharmacy Contractors are required to undertake will be notified in writing by the Commissioner.
- 5.6 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.

6 Patient access

- 6.1 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.
- 6.2 The Pharmacy Contractor must offer Covid-19 vaccinations through the NBS and may offer seasonal influenza vaccinations and co-administered Covid-19 and seasonal influenza vaccinations through the NBS. They 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.
- 6.3 The Pharmacy Contractor must offer vaccinations through advertised walkin 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.
- 6.4 The Pharmacy Contractor must minimise Covid-19 vaccine wastage and support the high uptake of vaccinations.

7 Assessment and consent

- 7.1 The Pharmacy Contractor must have in place a process to ensure that they comply with all relevant clinical checklists published by the Commissioner including checklists relevant to the vaccination of those under 18 years of age.
- 7.2 Where a Patient is aged under 18 years, the Pharmacy Contractor has complied with the provisions at paragraph 7.1, and the Commissioner has confirmed in writing that the Pharmacy Contractor may administer vaccinations to Patients of the relevant age group, this may only occur where

the Patient has been assessed as competent to consent and does consent, or is not assessed as competent but does not object and consent is provided by somebody with parental responsibility.

- 7.3 Prior to administering a vaccination, the Pharmacy Contractor must ensure that:
 - 7.3.1 a registered healthcare professional, trained in vaccine 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. This assessment should include providing reasonable information that the Patient may require to make a final decision on whether to proceed with the vaccination; and
 - 7.3.2 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) must be 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.
- 7.4 The Pharmacy Contractor must 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.
- 7.5 Each Patient being administered a vaccine must be given written information about the vaccine as specified by UKHSA.² 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).

² <u>https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination</u>

8 Vaccine administration

- 8.1 The Pharmacy Contractor must ensure that vaccinations offered pursuant to this ES are provided in line with guidance in the Green Book, including relevant details on the treatment of anaphylaxis and secure storage and disposal of clinical waste. Pharmacy Contractors must ensure that they have a process in place to check any updates to the Green Book.
- 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 advice and guidance from Specialist Pharmacy Service (SPS)³;
 - 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 Where the vaccine is part of a multi-dose regimen, the Pharmacy Contractor must ensure 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 the subsequent dose(s).

³ <u>https://www.sps.nhs.uk/articles/safe-practice-for-handling-multiple-covid-19-vaccines/</u>

9 Vaccine handling and storage

- 9.1 Vaccines offered to Patients pursuant to this ES must be received, stored, and prepared (and transported, where relevant) in accordance with the relevant manufacturer's, the UKSHA's, MHRA's and the Commissioner's instructions, 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.
- 9.2 Covid-19 vaccines:
 - 9.2.1 are allocated to the Pharmacy Contractor operating specific Designated Sites, and the Pharmacy Contractor must not share the vaccine with other providers providing a similar vaccination service, or move the vaccine to other Designated Sites, without the express prior consent of the Commissioner;
 - 9.2.2 will be supplied to the Designated Site. A corresponding volume of needles / syringes will also be provided. The Pharmacy Contractor will be responsible for the supply of other consumables as may be required (for example PPE and items related to Infection Prevention and Control). The Pharmacy Contractor must be available to accept vaccine deliveries at the Designated Site according to the delivery schedule provided by the Commissioner;
 - 9.2.3 can be administered at locations other than the Designated Site with the prior consent of the Commissioner. Guidance published by the Commissioner on roving and mobile models must be followed if consent is provided by the Commissioner to enable the Pharmacy Contractor to adopt such models of delivering this ES.⁴;
 - 9.2.4 availability and supply may be constrained and is subject to change over time. The Commissioner may (acting reasonably) need to make

⁴ <u>https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-roving-and-mobile-models/</u>

allocation decisions regarding the vaccine during the term of this ES. Allocation decisions may include prioritising vaccine to particular providers or the use of a particular type of vaccine;

- 9.2.5 shall be administered in accordance with the Site Capacity of vaccinations. Where possible, the Commissioner shall endeavour to supply the necessary vaccine to enable this level of administration of vaccinations; and
- 9.2.6 must be offered through appointments as agreed (in number) with the Commissioner and in accordance with the number of vaccine(s) that the Commissioner will endeavour to supply.
- 9.3 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.
- 9.4 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.
- 9.5 Vaccine stock updates and wastage must be reported weekly or as is reasonably requested by the Commissioner.

10 Record keeping

10.1 The Pharmacy Contractor must maintain appropriate records to ensure effective ongoing delivery and governance, including in relation to paragraph

9.3, section 10 and 11 of this ES. Records must be managed in line with 'Records Management Code of Practice for Health and Social Care.⁵

- 10.2 Access to an online Point of Care System for making records of vaccinations will be provided by the Commissioner. The Pharmacy Contractor must ensure that any staff recording the vaccination have received relevant training to be able to update records appropriately and accurately.
- 10.3 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.
- 10.4 Only one Point of Care System must be used to record vaccinations in any calendar month, except where it is necessary to make amendments to previously recorded vaccination events, or where this has been agreed with the Commissioner during the transition to a new Point of Care System.
- 10.5 Pharmacy Contractors 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 System⁶. 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.
- 10.6 Where a record of the vaccination needs amending or has not been created on the Point of Care system, the Pharmacy Contractor shall be responsible for undertaking the amendment or creation as soon as reasonably possible following notification that the record contains an error.

⁵ <u>https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-and-social-care</u>

⁶ <u>https://digital.nhs.uk/coronavirus/vaccinations/training-and-onboarding/point-of-care#point-of-care-options-by-delivery-model</u>

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

11 Governance and accountability

- 11.1 The Responsible Pharmacist at the registered pharmacy premises is professionally responsible for the safe delivery of the 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 General Pharmaceutical Council 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.
- 11.2 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.
- 11.3 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.
- 11.4 The Pharmacy Contractor must report any Patient safety incidents in line with the Standard Operating Procedure.⁷

⁷ <u>https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-management-of-covid-19-vaccination-clinical-incidents-and-enquiries/</u>

- 11.5 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'⁸ report submitted.
- 11.6 The Pharmacy Contractor must co-operate with others in so far as it is reasonable, including any other person responsible for the provision of services pursuant to the COVID-19 vaccination programme, or for the provision of any subsequent doses of the vaccine after the termination of this ES, in a timely and effective way and give to others such assistance as may reasonably be required to deliver the services under this ES.

12 Training

- 12.1 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 Protocols⁹).
- 12.2 Pharmacy Contractors will be expected to oversee and keep a record to confirm that all staff have undertaken 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.
- 12.3 All persons involved in the preparation of vaccine must be appropriately trained in 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.
- 12.4 The Pharmacy Contractor must ensure that all persons involved in the administration of vaccines have received appropriate and adequate training and are competent in the administration of those vaccines. All persons involved in the administration of the vaccine must:

⁸ <u>https://yellowcard.mhra.gov.uk/</u>

⁹ https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanisms/

- 12.4.1 have completed the additional online Covid-19 specific training modules available on the e-learning for healthcare website¹⁰;
- 12.4.2 have the necessary experience, skills and training¹¹ including training with regard to the recognition and initial treatment of anaphylaxis;
- 12.4.3 refer and administer the vaccine in accordance with the most up to date version of the clinical guidance available including the relevant chapter of the Green Book;
- 12.4.4 be authorised and have understood the appropriate legal mechanism for administration of the vaccine (for example, the UKHSA Patient Group Directions or National Protocols)¹²; and
- 12.4.5 ensure that relevant staff are aware of, and take steps to reduce, risks associated with the handling of different vaccine types such as is outlined in the SPS guidance¹³.

13 Premises requirements

- 13.1 The Pharmacy Contractor will propose the location of the Designated Site, which shall be agreed with the Commissioner prior to commencement of the administration of vaccinations and in accordance with the Community Pharmacy Expression of Interest Process.¹⁴ The Pharmacy Contractor shall not change the location of the Designated Site without the prior written agreement of the Commissioner.
- 13.2 Where the Designated Site is not the registered pharmacy, it will be classed as an associated premises to the registered pharmacy and subject to GPhC regulation including standards for registered pharmacies.

¹⁰ https://portal.e-lfh.org.uk/Component/Details/675208

¹¹ https://www.gov.uk/government/publications/covid-19-vaccinator-training-

recommendations/training-recommendations-for-covid-19-vaccinators

¹² https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanism

¹³ https://www.sps.nhs.uk/articles/safe-practice-for-handling-multiple-covid-19-vaccines/

¹⁴ <u>https://www.england.nhs.uk/coronavirus/publication/community-pharmacy-national-enhanced-service-covid-19-vaccination-programme/</u>

- 13.3 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.
- 13.4 Prior to the Service Commencement Date and throughout the term of this arrangement, 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.
- 13.5 The Commissioner may be able to provide support to Pharmacy Contractors by way of equipment loan. Where such support is made available, all equipment will be maintained by the Pharmacy Contractor and shall be returned to the Commissioner at the end of the delivery of services under this ES.
- 13.6 Vaccinations administered in accordance with this ES must be administered at the Designated Site unless specific agreement is provided, in advance, by the Commissioner setting out the circumstances in which a vaccination can occur at a different location (for example, as a "pop-up" site to improve vaccination uptake at alternative premises at given date(s) and/or time(s) or a mobile model to permit vaccination of specific Patient groups).
- 13.7 Vaccinations must take place in a consultation room wherever the patient expresses this preference. Vaccinations can also 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.
- 13.8 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 in the Patient's home, a long-stay care home, or a long-stay residential

facility, the Pharmacy Contractor must make these arrangements within 8 weeks, or as soon as reasonably possible, as agreed in advance with the Commissioner.

- 13.9 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.
- 13.10 The Pharmacy Contractor must ensure appropriate processes are in place to dispose of any clinical waste, vaccine packaging and PPE used during the vaccination process.
- 13.11 The Pharmacy Contractor is required to comply with reasonable requests from the Commissioner (NHSE) 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).

14 Service availability

- 14.1 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 minimum number of vaccines the site has been commissioned to deliver, JCVI guidance on dosing intervals, the size of the local population eligible for vaccination and available vaccine supply.
- 14.2 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.
- 14.3 The Pharmacy Contractor must ensure that they have in place suitable arrangements to prevent the disruption of other services or obligations placed on the Pharmacy Contractor by the Community Pharmacy

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

- 14.4 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.
- 14.5 Where a Pharmacy Contractor is unable to, or appears unlikely to meet the agreed vaccination volumes, the Commissioner may require the Pharmacy Contractor to provide, within the timescale determined by the Commissioner, explanation and feedback. The Commissioner may, by written notice to the Pharmacy Contractor, terminate this ES immediately or on such notice as the Commissioner deems appropriate if the Commissioner is satisfied that the Pharmacy Contractor is no longer able to meet the requirements of this ES.

15 Payment arrangements¹⁵

- 15.1 Claims for item of service payments for this ES set out in paragraph 15.2 must be made via the Manage Your Service (MYS) platform 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.
- 15.2 In consideration of the Pharmacy Contractor's provision of this ES in accordance with the terms of this ES, the Commissioner will pay:
 - 15.2.1 an item of service payment of £7.54 per administration of a vaccination to each Patient; and
 - 15.2.2 £10.00 shall be payable to the Pharmacy Contractor for administration of each vaccination to each Patient where:

¹⁵ For further information on payments please see the Community Pharmacy Finance and Payments Guidance available here: <u>https://future.nhs.uk/CovidVaccinations</u>

- 15.2.2.1 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;
- 15.2.2.2 that Patient requires administration of a vaccination; and
- 15.2.2.3 the Pharmacy Contractor has recorded the status of the Patient in the Point of Care System prior to making the claim for payment.
- 15.3 Additional funding may be available from the Commissioner where the Pharmacy Contractor meets the requirements of the Financial and Payments Guidance for NHS Regional Teams, available on <u>FutureNHS</u>. Pharmacy Contractors must seek pre-authorisation from the Commissioner before incurring any costs that they intend to claim and provide associated evidence or invoices within four weeks of pre-authorisation.
- 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 at the time the vaccine was administered;
 - 15.4.2 the Pharmacy Contractor has used a vaccine supplied and recommended in accordance with the COVID-19 vaccination programme;
 - 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 as set out at paragraph 15.2;

- 15.4.4 the Pharmacy Contractor did not receive and did 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 15.1.
- 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 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 they meet the requirements of this ES.
- 15.7 If the Commissioner makes a payment to a Pharmacy Contractor under this ES and:
 - 15.7.1 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;
 - 15.7.2 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
 - 15.7.3 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 contractor must pay to the Commissioner that equivalent amount.

15.8 The Commissioner may, at its discretion, make additional payments to Contractors to support the delivery or incentivise the administration of vaccinations, in particular to underserved groups and in exceptional circumstances. Details of those additional payments will be made available at https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/primary-care-guidance/

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