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# Community Pharmacy National Enhanced Service

COVID-19 vaccination programme: September 2022 to **31 August 2023**

Version 2.0, 21 March 2023

Updates to the previous version are **highlighted in yellow**

# Community Pharmacy National Enhanced Service Agreement

COVID-19 vaccination programme: September 2022 to 31 August 2023

Version 2.0

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Version updates: (changes in version 2.0 are marked in yellow)

Version	Updated section
2.0	Page 1,2 [updates] Page 4 [addition], 5 [update], 2.2.3 [addition], 2.2.4 [update], 2.2.6 [update], 2.2.16 [addition] 9.2.2 [updated footnote], 13.4.4.2 [updated footnote], 13.4.5.2 [updated footnote], 14.6 [update], 16 [revised terminology throughout and additions]

## 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 local population need, where Pharmacy Contractors can meet the key designation requirements and where NHS England considers the Pharmacy Contractor is best placed to meet that need. The service will be provided as a National Enhanced Service (“an ES”), commissioned by NHS England in consultation with the Pharmaceutical Services Negotiating Committee.

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, the public and patients. It is a national specification that cannot be varied locally.

NHS England will also commission an Enhanced Service from general practices. Pharmacy Contractors who are not commissioned by NHS England to provide this ES are encouraged to discuss collaboration with their local Primary Care Network Grouping to support it to deliver maximum vaccine uptake.

**This ES relates to the period from 1 September 2022 to 31 August 2023 for COVID-19 vaccinations only (having been extended from an original end date of 31 March 2023).** Where a Pharmacy Contractor has previously delivered COVID-19 vaccination services under a Local Enhanced Service there is an expectation that the Pharmacy Contractor and the Commissioner shall agree to the termination of that Local Enhanced Service prior to the Commencement Date of this ES and all Patients will be vaccinated under this ES.

# 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 services 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 2022]
Commissioner	NHS England (previously known as, the NHS Commissioning Board known as “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: September 2022 to 31 August 2023
Designated Site	[insert address of the Designated Site]
Service Payment	Means the payment set out at paragraph 16.

Site Capacity	<b>[Insert number of vaccinations per week]</b> 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 “**Adult Care Home**” refers to a location which provides both accommodation and personal care together and is a person’s sole place of residence. It encompasses both older adult and non-older adult care homes. This excludes supported living and respite care;

2.2.2 “**Completed Adult Care Home**” status refers to when all residents of the Adult Care Home that are eligible for vaccination, and have consented to be vaccinated, have been vaccinated (unless personalised care adjustments apply);

2.2.3 “**Completed Older Adult Care Home**” status refers to when all residents of the Older Adult Care Home that are eligible for vaccination, and have consented to be vaccinated, have been vaccinated (unless personalised care adjustments apply);

2.2.4 “**Commissioner**” means NHS England (previously the National Health Service Commissioning Board, known as NHS England);

2.2.5 “**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;

2.2.6 “**End Date**” means 31 August 2023 unless terminated earlier in accordance with paragraph 3.7 or otherwise in accordance with this ES;

2.2.7 “**GPhC**” means the General Pharmaceutical Council;

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 “**Local Enhanced Service or LES**” means to the previous community pharmacy local enhanced service: COVID-19 Vaccination programme: phases 1 & 2 & phase 3;
- 2.2.11 “**LES 2020/21 (phase 1 & 2)**” means the Local Enhanced Service: COVID-19 vaccination programme 2020/21;
- 2.2.12 “**LES 2021/22 (phase 3)**” means the Local Enhanced Service: COVID-19 vaccination programme 2021/22;
- 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 (NBS)**” means the service linked to the call/recall services and used by Patients to book coronavirus (COVID-19) vaccination appointments;
- 2.2.16 “**Older Adult Care Homes**” means a location which provides both accommodation and personal care together, is a person’s sole place of residence and is for adults aged 65 or over. This excludes supported living and respite care and non-older adult care homes;
- 2.2.17 “**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;
- 2.2.18 “**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 Regulations”** means the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, as amended;
- 2.2.21 **“Phase”** means Phase 1 which was the vaccination of Patient JCVI cohorts 1-9. Phase 2 which was the vaccination of Patient JCVI cohorts 10-12. Phase 3 which was the administration of booster vaccinations starting in September 2021. Phase 4 which was used in the GP ES to refer to additional vaccinations in spring 2022;
- 2.2.22 **Point of Care System** means a clinical system that has been assured by NHS Digital to record COVID-19 vaccination events;
- 2.2.23 **“Selection Process”** refers to the process whereby the Pharmacy Contractor is selected to deliver services under this ES;
- 2.2.24 **“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;
- 2.2.25 **“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;
- 2.2.26 **“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 3.7. The Commissioner shall be entitled to extend the term on one or more occasions by notifying the Pharmacy Contractor provided that the duration of this ES shall be no longer than one year.
- 3.2 From 1 January 2023, 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”).
- 3.3 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 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.
- 3.5 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.
- 3.6 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.

- 3.7 This ES may be terminated on any of the following events:
- 3.7.1 automatically when the COVID-19 vaccination programme comes to an end;
  - 3.7.2 by the Commissioner providing not less than 42 days' notice to the Pharmacy Contractor;
  - 3.7.3 by the Pharmacy Contractor providing not less than 42 days' notice to the Commissioner, unless otherwise agreed with the Commissioner;
  - 3.7.4 immediately on removal of either the Pharmacy Contractor from the Pharmaceutical List or, if there are more than one premises in relation to the Pharmacy Contractor, the removal of the Designated Premises from the Pharmaceutical List at or from which the Pharmacy Contractor provides the ES pursuant to this ES;
  - 3.7.5 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 15.5; or
  - 3.7.6 where the Pharmacy Contractor does not commence the administration of vaccinations in accordance with paragraphs 4.4 and 4.5.

## 4 Service description

- 4.1 The COVID-19 Vaccination Programme has been established to enable the safe administration of COVID-19 vaccinations to Patients in England.
- 4.2 Vaccinations will be provided to eligible Patients in JCVI Cohorts from a variety of providers, who must be prepared to administer vaccines in a way that minimises waste and makes best use of available supply.

- 4.3 The Pharmacy Contractor must comply with the 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 Selection Process.
- 4.4 Subject to paragraph 10.5, the Pharmacy Contractor may administer vaccinations in accordance with this ES from the Commencement Date.
- 4.5 The Pharmacy Contractor must commence the administration of vaccinations within 4 weeks of the date notified by the Commissioner for the commencement of the vaccinations. 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 date notified by the Commissioner for the commencement of the vaccinations. 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 time-frames will result in termination of the ES on a date to be notified by the Commissioner to the Pharmacy Contractor.
- 4.6 Where it is operationally expedient, co-administration of the COVID-19 vaccine and the seasonal influenza vaccine or other vaccinations commissioned from the Pharmacy Contractor should be provided if possible, in order to maximise efficiency for the Pharmacy Contractor and minimise the number of attendances required for Patients to receive these vaccinations. Co-administration shall at all times be in line with the provisions set out in the Green Book<sup>1</sup>.
- 4.7 Where appropriate<sup>2</sup> 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

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<sup>1</sup> <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

<sup>2</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 4.7, the Pharmacy Contractor can advise the Patient via its established non-in person procedures.

providers of those services in the local area, signposting to an online list of services in the local area and general advice and guidance.

- 4.8 The Pharmacy Contractor must not use provision of this ES as an opportunity to attempt to influence or seek to persuade a Patient to change their choice of pharmacy, or to seek to change any prescription nominations the Patient may already have in place with other Pharmacy Contractors under the Community Pharmacy Contractual Framework.
- 4.9 The Pharmacy Contractor must not use provision of this ES as an opportunity to attempt to influence or seek to persuade a Patient to participate in, or obtain, a Patient-funded service provided by the Pharmacy Contractor.

## 5 Aims and intended outcomes

- 5.1 The aims of this service are to:
  - 5.1.1 maximise uptake of COVID-19 vaccine by Patients by providing vaccination services from Pharmacy Contractors where a need is identified by the Commissioner;
  - 5.1.2 administer vaccines as recommended by the JCVI;
  - 5.1.3 increase opportunities for Patients to receive COVID-19 and influenza and/or other relevant vaccinations within the same location; and
  - 5.1.4 ensure that vaccination services can be provided from a variety of settings and effectively utilising available staff from across primary care.

## 6 Patient eligibility

- 6.1 The Pharmacy Contractor may 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.
- 6.2 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.
- 6.3 The Pharmacy Contractor must administer the vaccinations to Patients in the priority order announced and authorised by the Commissioner.
- 6.4 The Pharmacy Contractor must:
  - 6.4.1 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 a protected characteristic, as outlined in the Equality Act (2010). This includes Age, Disability, Gender Reassignment, Marriage and Civil Partnership, Pregnancy and Maternity, Race, Religion or Belief, Sex or Sexual Orientation;
  - 6.4.2 only administer COVID-19 vaccinations to Patients who meet the requirements set out in the Green Book; and
  - 6.4.3 only administer vaccinations to Patients aged 18 years or over unless or until the provisions at paragraph 8.1 have been complied with and the Commissioner has indicated in writing that the Pharmacy Contractor may vaccinate those aged under 18 years of age.
- 6.5 If a prospective patient (or carer) enquires about individual eligibility for the delivery of the vaccination services, the Pharmacy Contractor must be able to provide accurate and up to date information, including advising on

eligibility for housebound vaccinations at the Patient's home by referral to their general practice.

- 6.6 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.
- 6.7 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.
- 6.8 Patients do not require an NHS number or GP registration to receive a vaccination and must not be denied vaccination on this basis.

## 7 Patient access

- 7.1 The Pharmacy Contractor must offer vaccinations through the NBS and 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.
- 7.2 The Pharmacy Contractor must 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.
- 7.3 The Pharmacy Contractor must support high uptake of vaccinations and minimise vaccine wastage by proactively contacting Patients for vaccinations where appropriate. This may be done, where appropriate by:
  - 7.3.1 making the availability and access routes to vaccination known to Patients who are being provided with other pharmaceutical services at the Pharmacy Contractor's registered premises;



- 7.3.2 contacting Patients to pull forward appointments where there would otherwise be wastage of resources in accordance with the Green Book;
- 7.3.3 contacting Patients who did not turn up for booked appointments and supporting them to rebook or obtain vaccination elsewhere; and/or
- 7.3.4 maintaining a list of Patients who have indicated that they could be contacted for an appointment at short notice to prevent the wastage of resources.

## 8 Assessment and consent

- 8.1 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.
- 8.2 Where a Patient is aged under 18 years, the Pharmacy Contractor has complied with the provisions at paragraph 8.1, 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.
- 8.3 Prior to administering a vaccination, the Pharmacy Contractor must ensure that:
  - 8.3.1 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

- 8.3.2 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.
- 8.4 Patient consent may be obtained verbally and must cover the administration of the vaccine as well as advising the Patient of information sharing that will take place for the appropriate recording of the vaccination in their GP practice record. The Patient must also be informed that information relating to their vaccination may be shared with the Commissioner (or the NHS Business Services Authority acting on their behalf) for the purposes of payment, post-payment verification, supply management and planning of future vaccination requirements.
- 8.5 Each Patient being administered a vaccine 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).

## 9 Vaccine administration

- 9.1 The Pharmacy Contractor must ensure that vaccinations offered pursuant to this ES are provided in line with guidance in immunisation against infectious disease (The Green Book<sup>4</sup>), 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.

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

<sup>4</sup> <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

- 9.2 The Pharmacy Contractor must follow all current guidance published by the JCVI, NHS England, MHRA and/or UKHSA on:
- 9.2.1 which vaccine is the most suitable for each Patient;
  - 9.2.2 handling and manipulation of the vaccine with reference to advice and guidance from Specialist Pharmacy Service (SPS)<sup>5</sup>;
  - 9.2.3 the intervals between doses where multiple doses are required;
  - 9.2.4 the number of doses of each vaccine required to achieve the desired immune response; and
  - 9.2.5 any other relevant guidance relating to the administration of the different types of vaccine and the different JCVI Cohorts from time to time.
- 9.3 In the event of a conflict between guidance issued by JCVI, NHS England, MHRA and/or UKHSA, NHS England shall confirm which guidance shall be adopted.
- 9.4 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 has understood 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).

## 10 Vaccine handling and storage

- 10.1 Vaccines offered to Patients pursuant to this ES must be received, stored, and prepared in accordance with any conditions set by the MHRA in relation to each vaccine, and in line with the manufacturer's, Health Education England's and the Commissioner's instructions and associated Standard Operating Procedures. Receipt, storage, transport and

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<sup>5</sup> <https://www.sps.nhs.uk/home/covid-19-vaccines/general-information-and-guidance/handling-multiple-covid-19-vaccines/>

preparation of vaccines used pursuant to this ES must also be undertaken with appropriate clinical oversight and in accordance with governance arrangements in place for this ES.

- 10.2 Vaccines 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.
- 10.3 Vaccines 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.
- 10.4 Vaccines can be administered at locations other than the Designated Site with the prior consent of the Commissioner. Where such consent is provided, 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 GPhC standards. 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.<sup>6</sup>
- 10.5 The Pharmacy Contractor acknowledges that vaccine availability and supply may be constrained and is subject to change over time. The Commissioner may need to make allocation decisions regarding the vaccine during the term of this ES. Allocation decisions may include prioritising vaccine to particular Designated Sites or localities or the use of a particular type of vaccine.
- 10.6 The Pharmacy Contractor has agreed that it shall administer the Site Capacity of vaccinations. Where possible, the Commissioner shall

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<sup>6</sup> <https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-roving-and-mobile-models/>

endeavour to supply the necessary vaccine to enable this level of administration of vaccinations.

- 10.7 On a regular basis the Pharmacy Contractor must agree with the Commissioner the number of appointments that will be made available by the Pharmacy Contractor for the administration of the vaccination in the proceeding period (to be agreed) and the vaccine(s) that the Commissioner will endeavour to supply.
- 10.8 The Pharmacy Contractor and the Commissioner may agree that a reduced capacity for the administration of vaccinations may be appropriate in defined periods where, for example, the reduced capacity enables the Pharmacy Contractor to vaccinate specific Patient groups (e.g., vaccination of rough sleepers in a given area over a given number of days). The Pharmacy Contractor will only receive Service Payments in respect of activity delivered.
- 10.9 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.
- 10.10 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.
- 10.11 Vaccine stock updates and wastage must be reported weekly or as is reasonably requested by the Commissioner.

# 11 Record keeping

- 11.1 The Pharmacy Contractor must maintain appropriate records to ensure effective ongoing delivery and governance of this ES.
- 11.2 Access to an online Point of Care System for making records of vaccinations will be provided by the Commissioner. The Pharmacy Contractor must adhere to defined standards of record keeping ensuring that clinical records are made on the system as soon as is reasonably possible after the vaccination is administered and before the end of the same day that the vaccination was administered. The Pharmacy Contractor must ensure that any staff recording the vaccination have received relevant training to be able to update records appropriately and accurately.
- 11.3 The defined standards of record keeping referred to in paragraph 11.2 must include use of 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.
- 11.4 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.
- 11.5 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.
- 11.6 The Pharmacy Contractor must maintain appropriate records, including records in relation to paragraphs 10.9, 11, and 12 of this ES.

## 12 Governance and accountability

- 12.1 The Pharmacy Contractor must have a named Clinical Lead for this ES within their organisation/pharmacy whose name shall be made available to the Commissioner on request. The Clinical Lead must be a pharmacist, registered with the GPhC, and trained in vaccinations (including having a clear understanding of the requirements of this ES). The Clinical Lead will be the lead contact for this ES for contractual and professional matters.
- 12.2 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.
- 12.3 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.
- 12.4 The Pharmacy Contractor must have systems in place to ensure that key information in relation to the delivery of this ES can be communicated and acted upon in a timely manner.
- 12.5 There is an expectation that this ES will operate as part of the wider NHS system in providing COVID-19 vaccinations, and the Pharmacy Contractor must work with Regional Pharmacy Teams and specialist pharmacy colleagues and the Specialist Pharmacy Service (SPS) to obtain advice and guidance where necessary.

- 12.6 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.
- 12.7 The Pharmacy Contractor must ensure that all staff are trained as appropriate to their role in delivering services in accordance with this ES and in line with paragraph 13.
- 12.8 The process for handling clinical incidents or enquiries related to the COVID-19 vaccination programme is explained in the Commissioner Standard Operating Procedure.<sup>7</sup> The Pharmacy Contractor must report any Patient safety incidents in line with the Standard Operating Procedure and in accordance with the clinical governance requirements of the Pharmacy Contractor's Terms of Service or Local Pharmaceutical Services contract (as appropriate).
- 12.9 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>8</sup> report submitted.
- 12.10 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.

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

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



## 13 Training

- 13.1 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 Protocols<sup>9</sup>).
- 13.2 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.
- 13.3 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.
- 13.4 All persons involved in the administration of the vaccine must have:
  - 13.4.1 completed the additional online COVID-19 specific training modules available on the e-learning for healthcare website when available;
  - 13.4.2 the necessary experience, skills and training to administer vaccines in general, including completion of the general immunisation training available on e-learning for healthcare and face-to-face administration training, where relevant;
  - 13.4.3 the necessary experience, skills and training, including training with regard to the recognition and initial treatment of anaphylaxis; and
  - 13.4.4 where a healthcare professional is administering the vaccine:
    - 13.4.4.1 read and understood the clinical guidance available and to be published on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/>;

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

13.4.4.2 understood and be familiar with the Patient Group Directions for the COVID-19 vaccines made available by UKHSA and authorised by the Commissioner<sup>10</sup> including guidance on who can use them  
<https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them>;  
and

13.4.4.3 ensured that registered healthcare professionals were involved in the preparation (in accordance with the manufacturer's instructions) of the vaccine(s) unless unregistered staff have been trained to do this; and

13.4.5 where any other persons are administering the vaccine:

13.4.5.1 be authorised, listed, referred to or otherwise indentified by reference to The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020;

13.4.5.2 while preparing and/or administering vaccinations be supervised by a healthcare professional fulfilling the requirements of paragraph 14.9; and

13.4.5.2 be familiar with, understand and act within the scope of the national protocol for the COVID-19 vaccines<sup>11</sup>, made available by the UKHSA and approved by the Secretary of State for Health and Social Care.

13.5 Pharmacy Contractors must ensure that staff are familiar with all guidance relating to the administration of the different types of vaccine and are capable of the delivery of vaccinations using the different types of vaccine.

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<sup>10</sup> <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanisms/patient-group-directions-pgds-for-covid-19-vaccines/>

<sup>11</sup> <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanisms/national-protocols-for-covid-19-vaccines/>

- 13.6 The Pharmacy Contractor must 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 Specialist Pharmacy Service guidance.<sup>12</sup>
- 13.7 The Pharmacy Contractor must ensure that staff are appropriately trained and understand what their role in the delivery of this ES requires, including working within the relevant systems and processes set out by the Pharmacy Contractor and understanding how to report concerns should any be identified.
- 13.8 The Pharmacy Contractor must ensure that staff are made aware of the risks associated with the handling and disposal of clinical waste and that correct procedures are used to minimise those risks. A needle stick injury procedure must be in place.
- 13.9 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).

## 14 Premises requirements

- 14.1 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 Site Selection Process.<sup>13</sup> The Designated Site must demonstrate good access for Patients and value for money. The Designated Site shall be at the registered pharmacy premises or other NHS premises unless authorised by the Commissioner through the Selection Process. The Pharmacy Contractor shall not change the location of the Designated Site without the prior written agreement of the Commissioner.

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<sup>12</sup> <https://www.sps.nhs.uk/home/covid-19-vaccines/general-information-and-guidance/handling-multiple-covid-19-vaccines/>

<sup>13</sup> <https://www.england.nhs.uk/coronavirus/publication/covid-19-vaccination-enhanced-service-specification-for-autumn-winter-2022-for-community-pharmacy/>

- 14.2 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.
- 14.3 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.
- 14.4 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. It is envisaged that equipment will not be supplied to low volume sites, unless there are exceptional circumstances.
- 14.5 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).
- 14.6 Where a Patient is unable to access the Designated Site, the Pharmacy Contractor must 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 within 8 weeks or as soon as reasonably possible as agreed in advance with the Commissioner.
- 14.7 Prior to service commencement in accordance with paragraph 4.5 and throughout the term of this ES, 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 ES or to ensure that the services are being delivered in accordance with this ES. 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.

14.8 Vaccinations must only be offered where suitable facilities are available and Patient dignity and confidentiality can be respected. The minimum requirements include:

14.8.1 meeting the GPhC premises standards;

14.8.2 the area where vaccines are administered must be distinct from the general public areas;

14.8.3 maintenance of Infection Prevention and Control Standards; and

14.8.4 there is a suitable area where Patients can be observed after vaccination as advised by the MHRA or if necessary for that individual. This area must have:

14.8.4.1 access to appropriate equipment such as adrenaline/anaphylaxis kits; and

14.8.4.2 personnel suitably trained in basic life support techniques, and in recognising and responding to anaphylaxis, to provide care should the Patient suffer an adverse reaction to the vaccination.

14.9 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.

14.10 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.

14.11 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).

## 15 Service availability

- 15.1 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.
- 15.2 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.
- 15.3 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.
- 15.4 The Pharmacy Contractor must co-ordinate with the regional / ICS operations centre to plan appointments / clinics according to expected vaccine supply and amend those schedules if there is a disruption to supply or requirement to Surge. 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.
- 15.5 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.

## 16 Payment arrangements<sup>14</sup>

- 16.1 Claims for Service Payments for this ES set out in paragraph 16.3.1 and 16.3.2 must be made by the 5th of the following month via the Manage Your Service (MYS) platform provided by the NHS Business Services Authority (the NHSBSA). Claims will only be accepted by the NHSBSA if they are submitted within three months of administration of the vaccination. Any claims that are submitted later than three months following administration of the vaccination will not be processed and the Pharmacy Contractor will not receive any Service Payment for those vaccinations. Payment of Adult Care Home **additional payments** only as set out in paragraph 16.3.3 is made on the basis of a real-time return which must be completed and submitted in the timescales set out in paragraph 16.3.3.3 Further detail is provided in the PCN Finance and Payments Guidance available at <https://future.nhs.uk/CovidVaccinations/view?objectID=38665872>.
- 16.2 Service Payments will be made according to the FP34 Schedule of Payments. Claims will show on payment schedules under the 'COVID Vaccine' header.
- 16.3 In consideration of the Pharmacy Contractor's provision of this ES in accordance with the terms of this ES, the Commissioner will pay:
- 16.3.1 an item of service payment of £10.06 per administration of a vaccination to each Patient; and
- 16.3.2 £10.00 shall be payable to the Pharmacy Contractor for administration of each vaccination to each Patient where:

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<sup>14</sup> For further information on payments please see the Community Pharmacy Finance and Payments Guidance available here: [https://future.nhs.uk/P\\_C\\_N/view?objectId=24732112](https://future.nhs.uk/P_C_N/view?objectId=24732112)

- 16.3.2.1 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;
- 16.3.2.2 that Patient requires administration of a vaccination; and
- 16.3.2.3 the Pharmacy Contractor has recorded the status of the Patient in the Point of Care System prior to making the claim for payment.
- 16.3.3 A one-off Adult Care Home **additional payment** will be payable to the Pharmacy Contractor for each Completed Adult Care Home that is confirmed to the Commissioner by real-time return<sup>15</sup> no later than 23:59 on 30 October 2022 where:
- 16.3.3.1 the Pharmacy Contractor has agreed with the Commissioner in accordance with paragraph 14.6 to offer vaccination to the residents of an Adult Care Home; and
- 16.3.3.2 the Adult Care Home has achieved Completed Adult Care Home status by no later than 23:59 on 23 October 2022; and
- 16.3.3.3 the Pharmacy Contractor has completed a real-time survey return and submitted it to the Commissioner as soon as reasonably possible after the Adult Care Home became a Completed Adult Care Home, which ideally will be at the time of the visit to the Adult Care Home at which the vaccinations are administered but must be submitted before the end of seven calendar days following achievement of Completed Adult Care Home status.

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<sup>15</sup> <https://forms.necsu.nhs.uk/autumn-winter-care-home-visits/>



16.3.4 Where the Pharmacy Contractor meets the conditions in paragraph 16.3.3 the additional payments that shall be payable for each Completed Care Home will be:

16.3.4.1 A “Small Adult Care Home” additional payment of £150 where the Completed Adult Care Home has between 1 and 10 beds;

16.3.4.2 A “Medium Adult Care Home” additional payment of £275 where the Completed Adult Care Home has between 11 and 49 beds;

16.3.4.3 A “Large Adult Care Home” additional payment of £400 where the Completed Adult Care Home has between 50 and 149 beds; and;

16.3.4.4 A “Very Large Adult Care Home” additional payment of £525 where the Completed Adult Care Home has between 150 and 250 beds.

16.3.5 A one-off Spring/Summer Older Adult Care Home additional payment will be payable to the Pharmacy Contractor for each Completed Adult Care Home that is confirmed to the Commissioner by real-time return no later than 4 June 2023 where:

16.3.5.1 the Pharmacy Contractor has agreed with the Commissioner in accordance with paragraph 14.6 to offer vaccination to the residents of an Older Adult Care Home; and

16.3.5.2 the Older Adult Care Home has achieved Completed Adult Care Home status by no later than 23:59 on 28 May 2023; and

16.3.5.3 the Pharmacy Contractor has completed a real-time survey return and submitted it to the Commissioner as soon as reasonably possible after the Older Adult Care Home became a Completed Older Adult Care Home, which ideally will be at the time of the visit to the Older Adult Care Home at which the vaccinations are administered but must be

submitted before the end of seven calendar days following achievement of Completed Older Adult Care Home status.

16.3.6 Where the Pharmacy Contractor meets the conditions in paragraph 16.3.5 the additional payments that shall be payable for each Completed Older Adult Care Home will be:

16.3.6.1 A “Small Older Adult Care Home” additional payment of £150 where the Completed Older Adult Care Home has between 1 and 10 beds; and

16.4 16.3.6.2 A “Medium Older Adult Care Home” additional payment of £275 where the Completed Older Adult Care Home has between 11 and 49 beds. The vaccines made available under this ES will be provided to the Pharmacy Contractor free of charge, and therefore no reimbursement of the cost of the vaccine is payable.

16.5 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 [FutureNHS](#). 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.

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

16.6.1 the Patient in respect of whom payment is being claimed was within one of the eligible JCVI Cohorts and that JCVI Cohort was announced and authorised by the Commissioner at the time the vaccine was administered;

16.6.2 the Pharmacy Contractor has used a vaccine supplied in accordance with the COVID-19 vaccination programme;

16.6.3 the administration of the vaccination has been recorded on the specified Point of Care System on the day of the administration of the vaccination to the Patient;

16.6.4 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;

16.6.5 the claim for payment was submitted in accordance with paragraph 16.1; and

16.6.6 Payment of Care Home additional payments only as set out in paragraph 16.3.3 and 16.3.5 are made on the basis of a live time return which must be completed and submitted in the timescales set out in paragraphs 16.3.4 and 16.3.6. Further detail is provided in the PCN Finance and Payments Guidance available at

<https://future.nhs.uk/CovidVaccinations/view?objectID=38665872>.

16.7 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.

16.8 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.

16.9 If the Commissioner makes a payment to a Pharmacy Contractor under this ES and:

16.9.1 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;

16.9.2 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

16.9.3 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 contractor must pay to the Commissioner that equivalent amount.

16.10 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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