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# Community pharmacy local enhanced service

COVID-19 vaccination programme: phase 3 2021/22

Version 5

## Community Pharmacy local enhanced service

### COVID-19 vaccination programme: phase 3

#### **Equalities and health inequalities statement**

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

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# Introduction

The NHS is a global leader in achieving high levels of vaccination coverage, and this has been reflected in a hugely successful COVID-19 vaccination programme. Between 8 December 2020 and 14 September 2021 over 36 million Patients in England have been vaccinated with two doses of COVID-19 vaccine, with over 40 million having received one dose of the COVID-19 vaccine.

Community pharmacy has played a critical role in the success of phase 1 (the vaccination of patient JCVI cohorts 1-9) and phase 2 (the vaccination of patient JCVI cohorts 10-12) of the COVID-19 vaccination programme. Through their strong relationships in local places and neighbourhoods, community pharmacies have helped to tackle vaccine inequalities and improve vaccination take-up.

This next and third phase of the COVID-19 vaccination programme will offer revaccination boosters (with additional vaccine) for those at the highest risk, to maintain protection against the risk of severe illness, and continue to offer initial vaccinations to those Patients who did not take up or were previously not eligible to receive vaccination in phases 1 and 2.

The COVID-19 vaccination programme: phase 3 will be delivered alongside the seasonal influenza vaccination programme, which runs each autumn. Whilst the Commissioner (NHSE) has sought to streamline provisions as far as possible to enable Pharmacy Contractors to deliver these programmes alongside one another, these are separate programmes with separate contracting arrangements. Together, the vaccinations will offer those at highest risk safe and effective protection against the risks of COVID-19 and seasonal influenza.

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 contractor best placed to meet that need. The service will be provided as a Local Enhanced Service (LES), commissioned by NHS England in consultation with the relevant Local Pharmaceutical Committees. This document is referred to as the LES Agreement.

This LES Agreement provides Pharmacy Contractors with operational certainty whilst also noting that some requirements and timescales may be subject to change.

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

This LES Agreement relates to phase 3 COVID-19 vaccinations only. Where a Pharmacy Contractor has previously delivered services under the Local Enhanced Service: COVID-19 vaccination programme 2020/21 (“the LES 2020/21 (phase 1 & 2)”), there is an expectation that the Pharmacy Contractor and the Commissioner shall agree to the termination of the LES 2020/21 (phase 1 & 2) and all Patients will be vaccinated under this LES Agreement.

A draft version of this LES Agreement was published by NHS England on 14 July 2021 when pharmacy contractors were invited to submit expressions of interest for the delivery of the phase 3 COVID-19 vaccination service. The Pharmacy Contractor acknowledges that this LES Agreement incorporates certain changes to the version published on 14 July 2021 which were considered necessary to clarify certain matters or to reflect changes made since 14 July 2021 to the national COVID-19 vaccination programme.

Other formats of this document are available upon request. Please send your request to: [england.pccovidvaccine@nhs.net](mailto:england.pccovidvaccine@nhs.net).

## Commonly used terms

- **Commissioner (NHSE)** – the NHS Commissioning Board, responsible for direct commissioning of pharmaceutical services, and referred to in this LES Agreement as “NHS England”
- **Designation Process** – the process whereby Pharmacy Contractors can be commissioned to deliver services under the LES
- **Designated Site** – a site nominated by a Pharmacy Contractor and selected and approved by the Commissioner (NHSE) as the premises from which the vaccination will be administered to Patients (unless otherwise approved by the Commissioner (NHSE)) and as further described in this LES Agreement
- **GPhC** – the General Pharmaceutical Council
- **JCVI** – the Joint Committee on Vaccination and Immunisation
- **JCVI Cohorts** the cohorts of Patients referenced following JCVI advice
- **Local Enhanced Service (LES)** – this community pharmacy local enhanced service: COVID-19 Vaccination programme: phase 3 2021/22
- **LES 2020/21 (phase 1 & 2)** – the Local Enhanced Service: COVID-19 vaccination programme 2020/21
- **MHRA** – the Medicines and Healthcare products Regulatory Agency
- **Ministerial Decision** – a decision issued by the Secretary of State for Health and Social Care
- **National Booking Service (NBS)** – service linked to the call/recall services where a Patient can book appointments for their COVID-19 vaccinations
- **Patient** – Patients eligible to receive the vaccination are those in JCVI Cohorts which have been announced and authorised by the Commissioner (NHSE) as eligible for the vaccination by the Pharmacy Contractor

- **Pharmaceutical List** – the pharmaceutical list prepared, maintained and published by NHS England pursuant to regulation 10(2)(a) of the Pharmacy Regulations
- **Pharmaceutical Services** – has the meaning set out in the Pharmacy Regulations
- **Pharmacy Regulations** – the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 as amended
- **Phase** – Phase 1 was the vaccination of Patient JCVI cohorts 1-9. Phase 2 was the vaccination of Patient JCVI cohorts 10-12. Phase 3 seeks to implement [interim advice from JCVI](#) on the COVID-19 booster programme.
- **Point of Care System** - a clinical system that has been assured by NHS Digital to record COVID-19 vaccination events
- **PPE** – personal protective equipment
- **UKHSA** – UK Health Security Agency (a successor in title to Public Health England (PHE))
- **Terms of Service** – the terms of service that the Pharmacy Contractor is required to adhere to as set out in the Pharmacy Regulations and this LES Agreement

In this LES Agreement words importing the singular include the plural and vice versa.

# 1 Agreement between the parties

Commissioner (NHSE)	NHS Commissioning Board (“NHS England”) Address for service of notice: [Insert]
Pharmacy Contractor	[Insert Pharmacy Contractor name’s (as set out in the relevant pharmaceutical list) and address]
Local Enhanced Service (LES)	Community pharmacy local enhanced service: COVID-19 Vaccination programme: phase 3 2021/22
Designated Site	[insert address of the Designated Site]
Commencement Date	[Insert local enhanced service commencement date]
End Date	The Commissioner (NHSE) and the Pharmacy Contractor have agreed that this LES Agreement shall be extended such that the End Date shall now be 30 September 2022 (unless terminated earlier in accordance with paragraph 1.9 or otherwise in accordance with this LES Agreement).
Review Date	[Insert review date, if there is one]
Service Payment	Means the payment set out at paragraph 15. — .
Site Capacity	means a [Low / Medium / High] volume site, which shall be prepared to administer [100/350/1000] vaccinations per week as agreed with the Commissioner (NHSE) and subject to vaccine supply.  [to be amended by the Commissioner (NHSE) in accordance with the following:  Low volume sites must be prepared to administer at least 100 vaccinations per week



	<p>Medium volume sites must be prepared to administer at least 350 vaccinations per week</p> <p>High volumes sites must be prepared to administer at least 1000 vaccinations per week.]</p>
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## Enhanced service terms

- 1.1 For the avoidance of doubt, this LES Agreement is the 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. It may be necessary to make amendments to this LES Agreement for example, where there is a change to the recommended JCVI advice, vaccines or where changes are necessary to maximise vaccine uptake or to the booking or Point of Care System. The Pharmacy Contractor agrees to provide the LES Agreement, including any variations and updates from the Commencement Date until the End Date, unless terminated earlier in accordance with the terms of this LES Agreement.
- 1.2 The Pharmacy Contractor shall provide the services in accordance with the terms of this LES Agreement and in full compliance with the Terms of Service or LPS contract terms that apply to the Pharmacy Contractor.
- 1.3 The Pharmacy Contractor must not use provision of this LES Agreement 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.
- 1.4 The Pharmacy Contractor must not use provision of this LES Agreement 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.
- 1.5 Where it is operationally expedient, co-administration of the COVID-19 vaccine and the seasonal influenza vaccine may 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.

- 1.6 Where appropriate<sup>1</sup> Pharmacy contractors can advise the Patient attending for vaccination at the Designated Site about other Community Pharmacy services that are available. This could include, but is not limited to, the provision of health promotion materials, details of services and providers of those services in the local area, signposting to an online list of services in the local area and general advice and guidance. This should include signposting for seasonal influenza vaccinations where the Patient indicates that they have not made arrangements for this vaccination and the Patient does not elect to have a co-administered vaccine (where the Pharmacy Contractor is able to offer this).
- 1.7 The Pharmacy Contractor shall provide the LES fully in accordance with the terms of this LES Agreement.
- 1.8 In consideration of the Pharmacy Contractor's provision of the LES in accordance with the terms of this LES Agreement, the Commissioner (NHSE) will pay the Service Payment to the Pharmacy Contractor in accordance with the terms of this LES Agreement.
- 1.9 Termination:
  - 1.9.1 The Pharmacy Contractor may terminate this LES Agreement by serving not less than 42 days' written notice on the Commissioner (NHSE) at the address set out in the table above. The Commissioner (NHSE) may, at their absolute discretion, agree a shorter notice period. Where, due to an emergency the Pharmacy Contractor is not able to provide this notice period, they should contact the Commissioner (NHSE) to agree an amended timeframe with them.

<sup>1</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 1.5, the Pharmacy Contractor can advise the Patient via its established non-in person procedures.

- 1.9.2 The Commissioner (NHSE) may terminate this LES Agreement by serving not less than 42 days' written notice on the Pharmacy Contractor at the address set out in the table above.
- 1.9.3 This LES Agreement shall terminate automatically on termination of the Pharmacy Contractor's LPS contract, or 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 LES pursuant to this LES Agreement.
- 1.10 This LES Agreement 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 LES Agreement to any other party without the prior written permission of the Commissioner (NHSE).
- 1.11 Except where it is expressly stated to the contrary, this LES Agreement does not give rise to any rights enforceable by any person who is not a party to it.
- 1.12 The Commissioner (NHSE) may propose an extension (of no more than six months) to this LES Agreement in writing to the Pharmacy Contractor. Where such extension is agreed by the Pharmacy Contractor, the parties to this LES Agreement will vary the End Date to reflect the term of the extension period.
- 1.13 During the period 1 April 2022 to 30 September 2022, where there is (in the reasonable view of the Commissioner (NHSE)) 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 (NHSE), the Commissioner (NHSE) may require the Pharmacy Contractor to suspend the vaccination services (a "Pause").
- 1.14 Where the Pharmacy Contractor does not agree to the Pause, they may provide evidence to the Commissioner (NHSE) 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 (NHSE) and the Commissioner (NHSE) shall,

acting reasonably, reconsider whether it remains appropriate to continue with the Pause.

1.15 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 (NHSE) in advance of such costs being incurred.

While the services are Paused the Commissioner (NHSE) 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.

**Signed for and on behalf of the Commissioner (NHSE):**

Signature .....

Name .....

Job title .....

Date .....

**Signed for and on behalf of the Pharmacy Contractor:**

Signature .....

Name .....

Job title .....

Date .....

# Service description

## 2 Service description and background

- 2.1 A COVID-19 Vaccination Programme: phase 3 has been established to enable the safe administration of COVID-19 vaccinations to Patients in England.
- 2.2 Vaccinations will be provided to eligible Patient 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.
- 2.3 Provision of the service must comply with the Standard Operating Procedure: COVID-19 local vaccination services deployment in community settings and as it is updated from time to time.
- 2.4 This description is intended to detail the requirements of the service that can be commissioned from Pharmacy Contractors by the Commissioner (NHSE). It may be subject to amendment from time to time as the vaccination programme develops.
- 2.5 The requirement to provide COVID-19 vaccination under this service will begin on the date to be notified to the Pharmacy Contractor in writing by the Commissioner (NHSE). The commencement date for vaccine delivery will not be less than 7 calendar days from the date of the written notification unless the parties agree a different date. If the parties agree prior to signature of this LES a date for the vaccination service to begin, the parties will deem that agreed date to be the date the vaccination service is to begin.
- 2.6 Where the Pharmacy Contractor considers that it is operationally expedient to do so the COVID-19 vaccine and the seasonal influenza vaccine may be co-administered. Co-administration shall at all times be in line with the provisions set out in the Green Book. The JCVI have advised that “the COVID-19 booster vaccine programme should [not] disrupt or delay deployment of the annual influenza vaccination programme”. Therefore, it is important individuals are offered their COVID-19 and influenza vaccine as soon as they are eligible, rather than delaying for the purpose of co-

administration. We recognise there will be some instances where a short delay will ensure that more individuals receive both vaccines, for example in care homes, and sites should use their discretion to maximise these opportunities.”

- 2.7 In the event of a conflict between guidance issued by these organisations, NHS England shall confirm which guidance shall be adopted.
- 2.8 The Pharmacy Contractor must commence vaccination within 4 weeks of the date notified to the Pharmacy Contractor by the Commissioner (NHSE). 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 to the Pharmacy Contractor by the Commissioner (NHSE). The Commissioner may agree with the Pharmacy Contractor an extension not exceeding 4 weeks. Failure to begin the administration of vaccinations within these time-frames will result in termination of the LES Agreement on a date to be notified by the Commissioner (NHSE) to the Pharmacy Contractor.

### 3 Aims and intended outcomes

- 3.1 The aims of this service are to:
  - 3.1.1 maximise uptake of COVID-19 vaccine by Patients in identified at-risk groups<sup>2</sup> by providing vaccination services from Pharmacy Contractors alongside other sites where a need is identified by the Commissioner (NHSE).
  - 3.1.2 administer vaccines as recommended by the JCVI as part of an initial course of vaccination, or any additional subsequent doses or revaccination boosters that may be recommended.
  - 3.1.3 increase opportunities for specified cohorts of Patients to access COVID-19 vaccinations and/or improve Patient convenience and choice.

<sup>2</sup>[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/948338/jcvi-advice-on-priority-groups-for-covid-19-vaccination-30-dec-2020.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/948338/jcvi-advice-on-priority-groups-for-covid-19-vaccination-30-dec-2020.pdf)

3.1.4 ensure that vaccination services can be provided from a variety of settings and effectively utilising available staff from across primary care.

## 4 Patient JCVI Cohorts and priority groups

4.1 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 to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age, employment or carer status. The Pharmacy Contractor must be prepared to provide COVID-19 vaccinations to any Patient in an authorised cohort, in priority order unless contraindicated. Patients, including homeless patients, do not require an NHS number or GP registration to receive a vaccination and should never be denied one on this basis.

4.2 The Pharmacy Contractor will only administer COVID-19 vaccinations to Patients who:

4.2.1 received an initial course of vaccination and are recommended by JCVI to receive subsequent vaccination(s);

4.2.2 did not complete an initial course of vaccination and are recommended by JCVI to receive a subsequent vaccination to complete the initial course;

4.2.3 were previously eligible to receive a course of vaccination but who chose not to take up the offer or were unable to take up the offer and are still eligible to receive an initial course of vaccination;

4.2.4 were previously not eligible to receive a course of vaccination but now meet the eligibility criteria set out by JCVI to receive an initial course of vaccination; and

4.2.5 are aged 16 years or over unless or until the provisions at paragraph 12.5.2 and/or 12.5.3 (as relevant) have been complied with and the Commissioner had indicated in writing that the Pharmacy Contractor may vaccinate those aged under 16 years of age.

- 4.3 The Pharmacy Contractor must only administer COVID-19 vaccinations to Patients who are in the JCVI Cohorts, decided by Ministerial Decision and announced **and** authorised by the Commissioner (NHSE). These eligible cohorts will be published on <https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation> and the Pharmacy Contractor will be notified by the Commissioner (NHSE) of amendments through our Primary Care Bulletin.
- 4.4 The Pharmacy Contractor acknowledges that the announced and authorised JCVI cohorts may change from time to time and that these changes will affect who is eligible to receive the vaccination from the Pharmacy Contractor. This change may occur where there is consolidation, expansion and reprioritisation of the JCVI cohorts. If a prospective patient 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.
- 4.5 Subject to paragraph 4.6, Pharmacy Contractors must administer the vaccinations to Patients within the JCVI cohorts in the priority order announced and authorised by the JCVI relevant to the vaccination they are due to receive.
- 4.6 Vaccination will be permitted to Patients outside of the announced JCVI Cohorts where the Pharmacy Contractor can demonstrate exceptional circumstances, that it is clinically appropriate and where resources would otherwise have been wasted. Examples of this may include:
- 4.6.1 to mitigate health inequalities, such as might occur in relation to access to healthcare or underserved ethnicities (with the agreement of the Commissioner (NHSE)); or
- 4.6.2 availability of suitable approved vaccines, for example for specific age cohorts.
- 4.7 The Pharmacy Contractor will not be eligible for a Service Payment for the administration of a vaccination to a person outside the announced and authorised JCVI Cohorts unless they are able to evidence, at the request of the Commissioner (NHSE) and to the reasonable satisfaction of the Commissioner (NHSE), that paragraph 4.6 applies.



## 5 Eligibility of patients

- 5.1 Subject to paragraph 5.4, the Commissioner (NHSE) will announce the authorisation of JCVI Cohorts for vaccination by Pharmacy Contractors using the Primary Care Bulletin.
- 5.2 Patients who have booked appointments with the National Booking Service (NBS) will ordinarily have eligibility confirmed prior to booking. Any additional checks on eligibility will be notified in writing by the Commissioner (NHSE).
- 5.3 The Pharmacy Contractor must ensure that any Patient whose appointments are not made through the National Booking Service are eligible for a vaccination as set out in this LES Agreement and that arrangements are made for administration of any subsequent dose(s) of a multi-dose regimen where appropriate.
- 5.4 Where the Pharmacy Contractor has complied with the provisions at paragraph 12.5.2, the Commissioner (NHSE) may request and the Pharmacy Contractor may agree to administer vaccinations to Patients aged 12 -15 years of age but only 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.
- 5.5 Where the Pharmacy Contractor has complied with the provisions at paragraph 12.5.3, the Commissioner (NHSE) may request and the Pharmacy Contractor may agree to administer vaccinations to Patients aged 5 -11 years of age but only 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.

## 6 Patient recruitment

- 6.1 When Patients are offered a vaccination by the national call/recall system they will be invited to make an appointment using the National Booking Service (NBS).

- 6.2 The Pharmacy Contractor must comply with the requirements of the National Booking Service, especially in uploading appointment / clinic times in a timely way to allow Patient bookings to take place.
- 6.3 The Pharmacy Contractor must only provide services to Patients under this LES Agreement where the Patient has made a booking through the National Booking Service unless:
  - 6.3.1 alternative arrangements to improve uptake or engagement with communities have been agreed with the Commissioner (NHSE);
  - 6.3.2 the Patient is unable or unlikely to use the National Booking Service; or
  - 6.3.3 appointments previously offered on the National Booking Service are unfilled and the Pharmacy Contractor is satisfied that the Patient is eligible to receive the vaccination in accordance with the eligibility criteria set out in this LES Agreement.
- 6.4 The Pharmacy Contractor must have suitable procedures in place to support access for Patients who are unable or unlikely to book through the National Booking Service. Acceptable reasons why a Patient is unable or unlikely to book through the National Booking Service includes but is not limited to persons who:
  - 6.4.1 cannot be authorised by the National Booking Service but who do fall into authorised and announced JCVI Cohorts (for example in certain circumstances front-line Health and Social Care Workers);
  - 6.4.2 do not have an NHS number;
  - 6.4.3 do not have easy access to the National Booking Service website and/or telephone booking line;
  - 6.4.4 require support with communication; and/or
  - 6.4.5 experience other difficulties in accessing healthcare.
- 6.5 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:

- 6.5.1 making the availability and access routes to vaccination known to Patients who are being provided with other pharmaceutical services at the registered premises;
- 6.5.2 contacting Patients to pull forward appointments where there would otherwise be wastage of resources in accordance with the Green Book; and/or
- 6.5.3 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.

## 7 Assessment and consent

- 7.1 Prior to administering a COVID-19 vaccination to a Patient, the Pharmacy Contractor must ensure that a registered healthcare professional, trained in vaccine administration and familiar with the characteristics of the vaccine being administered, assesses the Patient as suitable to receive a COVID-19 vaccination. This assessment should include providing reasonable information that the Patient may require to make a final decision on whether to proceed with the vaccination. Consent should be obtained from the Patient by the registered healthcare professional at this stage.
- 7.2 Patient consent must be obtained prior to the vaccine being administered and the Patient's consent to the vaccination (or the name of the person who gave consent to the vaccination on their behalf, including their 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.
- 7.3 At 16 years of age a young person is presumed in law to have the capacity to consent, so young people aged 16 or 17 years can and should consent to their own medical treatment.
- 7.4 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 NHS England (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.

- 7.5 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).
- 7.6 Where a Patient is aged 12 - 15 years of age the Pharmacy Contractor must at all times comply with the provisions of the clinical checklist for 12 - 15 year olds.
- 7.7 Where a Patient is aged 5 - 11 years of age the Pharmacy Contractor must at all times comply with the provisions of the clinical checklist for 5 - 11 year olds.

## 8 Vaccine administration

- 8.1 The Pharmacy Contractor must ensure that vaccinations offered pursuant to this LES Agreement 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.
- 8.2 The Pharmacy Contractor must follow all current guidance published by the JCVI, NHS England, 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 by healthcare professionals with the appropriate skills to do so with reference to advice and guidance from

<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>

[Specialist Pharmacy Services \(SPS\)<sup>5</sup>](#) and workforce considerations for [phase 3 children's vaccinations<sup>6</sup>](#);

- 8.2.3 the relevant maximum and minimum timescales for administration of each vaccine where multiple doses of the vaccine are required;
  - 8.2.4 the number of doses of each vaccine required to achieve the desired immune response;
  - 8.2.5 the required gap between doses of vaccine where multiple doses of the vaccine are required;
  - 8.2.6 any other relevant guidance relating to the administration of the different types of vaccine and the different JCVI Cohorts from time to time; and
  - 8.2.7 this guidance is subject to change as the vaccination programme develops.
- 8.3 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).
- 8.4 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 Vaccine handling and storage

- 9.1 Vaccines offered to Patients pursuant to this LES Agreement 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 (NHSE) instructions and associated standard operating procedures. Receipt, storage, transport and preparation of vaccines used pursuant to this LES Agreement must also be

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

<sup>6</sup> <https://future.nhs.uk/connect.ti/CovidVaccinations/view?objectId=108802789>

undertaken with appropriate clinical oversight and in accordance with governance arrangements in place for this LES Agreement.

- 9.2 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 (NHSE).
- 9.3 Vaccines will be supplied to the Designated Site by the COVID-19 Vaccination: phase 3 programme. 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 and other scheduled deliveries at the Designated Site according to the delivery schedule provided by the Commissioner (NHSE).
- 9.4 Vaccines can be administered at locations other than the Designated Site with the prior consent of the Commissioner (NHSE). 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 relevant General Pharmaceutical Council (GPhC) standards. [Guidance published by the Commissioner \(NHSE\) on roving and mobile models](#) must be followed if consent is provided by the Commissioner (NHSE) to enable the Pharmacy Contractor to adopt such models of delivering the LES Agreement.<sup>7</sup>
- 9.5 The Pharmacy Contractor acknowledges that vaccine availability and supply may be constrained and is subject to change over time. The Commissioner (NHSE) may need to make allocation decisions regarding the vaccine during the term of this LES Agreement. Allocation decisions may include prioritising vaccine to particular Designated Sites or localities or the use of a particular type of vaccine.

<sup>7</sup> <https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-roving-and-mobile-models/>

- 9.6 The Pharmacy Contractor has agreed that it shall administer the Site Capacity of vaccinations. Where possible, the Commissioner (NHSE) shall endeavour to supply the necessary vaccine to enable this level of administration of vaccinations.
- 9.7 On a regular basis (at least weekly) the Pharmacy Contractor must agree with the Commissioner (NHSE) the number of appointments that will be made available for the administration of the vaccination in the proceeding period (to be agreed) and the vaccine(s) that the Commissioner (NHSE) will endeavour to supply.
- 9.8 The Pharmacy Contractor and the Commissioner (NHSE) 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 (i.e. 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.
- 9.9 The Pharmacy Contractor must ensure that any refrigerator used to store vaccine has sufficient space to store up to three separate vaccine brands, 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.
- 9.10 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 does not exceed 5% of the total number of vaccines supplied and stock holdings of vaccine remain low to support the maximisation of vaccinations to the population.
- 9.11 Vaccine stock updates and wastage must be reported weekly or as is reasonably requested by the Commissioner (NHSE).

## 10 Record keeping

- 10.1 The Pharmacy Contractor must maintain appropriate records to ensure effective ongoing delivery and governance of this LES.
- 10.2 Access to an online Point of Care System for making records of vaccinations will be provided. 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.
- 10.2A The defined standards of record keeping referred to in paragraph 10.2 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.
- 10.3 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 (NHSE) during the transition to a new Point of Care System.
- 10.4 Where the Point of Care System is unavailable due to 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 (NHSE) 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.
- 10.5 A digital system linked to the Point of Care System will ordinarily update the general practice Patient records. Should this system fail then the Pharmacy Contractor will be required to take reasonable steps to provide information to assist with updating the general practice record as requested by the Commissioner (NHSE).



- 10.6 The Commissioner (NHSE) will normally be able to access automated activity information providing information regarding Patients who have received a vaccination. In the event of a system failure, the Pharmacy Contractor may be required to provide manually downloaded reports to the Commissioner (NHSE).
- 10.7 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 (NHSE). Where the registered pharmacy premises are the Designated Site, approval from the Commissioner (NHSE) of a change to the Designated Site will be required.
- 10.8 The Pharmacy Contractor must maintain appropriate records, including records in relation to paragraphs 9.9, 10, and 11 of this LES Agreement.

## 11 Governance and accountability

- 11.1 The Pharmacy Contractor must have a named Clinical Lead for this LES Agreement within their organisation/pharmacy whose name shall be made available to the Commissioner (NHSE) on request. The Clinical Lead must be a pharmacist, registered with the General Pharmaceutical Council (GPhC), and trained in vaccinations (including having a clear understanding of the requirements of this LES Agreement). The Clinical Lead will be the lead contact for this LES Agreement for contractual and professional matters.
- 11.2 The Responsible Pharmacist at the registered pharmacy premises is professionally responsible for the safe delivery of the LES Agreement at the Designated Site. If the Responsible Pharmacist is unable to provide sufficient supervision of the LES, 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 LES Agreement. A record must be maintained of who that person is at each site at all times and made available to the Commissioner (NHSE) on request.

- 11.3 If the Responsible Pharmacist would be unable to provide sufficient supervision of this LES, for example where the Designated Site is located in a location other than the main pharmacy premises, the on-site pharmacist(s) supervising the associated premises must be linked with the Responsible Pharmacist and Superintendent Pharmacist through an appropriate governance framework.
- 11.4 All persons involved in the provision of this LES Agreement (whether delivering vaccinations directly or supervising others providing vaccinations) must adhere to all relevant professional standards, regardless of the setting. Information on what is expected of Pharmacy Professionals involved in the delivery of this LES Agreement is available on the GPhC website: <https://www.pharmacyregulation.org/standards/guidance/qa-coronavirus/covid-19-vaccination-programme>
- 11.5 The Pharmacy Contractor must have signed up to receive the [NHS England and NHS Improvement Primary Care Bulletin](#)<sup>8</sup> so that key information in relation to the delivery of this LES Agreement can be communicated and acted upon in a timely manner.
- 11.6 There is an expectation that this LES Agreement 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 Services (SPS) to obtain advice and guidance where necessary.
- 11.7 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 LES Agreement, 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 LES Agreement.

<sup>8</sup> <https://www.england.nhs.uk/email-bulletins/primary-care-bulletin/>

- 11.8 The Pharmacy Contractor must ensure that all staff are trained as appropriate to their role in delivering services in accordance with this LES Agreement and in line with paragraph 12.
- 11.9 The process for handling clinical incidents or enquiries related to the COVID-19 vaccination programme is explained in the Commissioner (NHSE) [Standard Operating Procedure](#).<sup>9</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.
- 11.10 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>10</sup> report submitted.
- 11.11 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 LES Agreement, in a timely and effective way and give to others such assistance as may reasonably be required to deliver the services under this LES Agreement.

## 12 Training

- 12.1 Vaccinations must be administered by an appropriately trained member of staff authorised under an appropriate legal mechanism, for example the [Public Health England Patient Group Directions or National Protocols](#).<sup>11</sup>
- 12.2 The Pharmacy Contractor must retain records that demonstrate that, prior to participating in the administration of vaccinations (whether vaccinating Patients themselves or supervising persons administering vaccines), all

<sup>9</sup> <https://www.england.nhs.uk/coronavirus/publication/standard-operating-procedure-management-of-covid-19-vaccination-clinical-incidents-and-enquiries/>

<sup>10</sup> <https://yellowcard.mhra.gov.uk/>

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

**registered health professionals** (including locums and relief pharmacists) have:

- 12.2.1 read and understood the clinical guidance available and to be published on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/>;
  - 12.2.2 been made aware of, and comply with, the specific handling requirements and MHRA conditions associated with each of the vaccines being used under this LES Agreement;
  - 12.2.3 completed the COVID-19 vaccine specific training modules on the [e-learning for health website](#)<sup>12</sup> for all vaccines recommended by the JCVI for use in the COVID-19 vaccination programme: phase 3. The Pharmacy Contractor must oversee and keep a record to confirm that all registered healthcare professionals have undertaken the training prior to participating in administration of the vaccination. This includes any additional training associated with new vaccines that become available during the term of this LES Agreement;
  - 12.2.4 the necessary experience, skills and training to store, transport, handle, and administer vaccines in general, including completion of general immunisation training, for example that available on e-learning for health, and face-to-face administration training, where relevant;
  - 12.2.5 the necessary experience, skills and training, including training with regard to the recognition and initial treatment of anaphylaxis, including for those under 18 years of age; and
  - 12.2.6 become familiar with and understand the Patient Group Direction for the COVID-19 vaccines, made available by UKHSA and authorised the Commissioner (NHSE) and / or be familiar with a National Protocol for administration of any COVID-19 vaccination supplied and administered.
- 12.3 The Pharmacy Contractor must also retain records that demonstrate that, prior to participating in vaccination, **all other persons** administering the vaccine must:

<sup>12</sup> <https://www.e-lfh.org.uk/>

- 12.3.1 be legally authorised under the terms of The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020;
- 12.3.2 while preparing and/or administering vaccinations, be supervised by a healthcare professional fulfilling the requirements described above;
- 12.3.3 comply with the specific handling requirements of each of the vaccines being administered in accordance with this LES Agreement;
- 12.3.4 have completed the COVID-19 vaccine specific training modules available on the [e-learning for health website](#).<sup>13</sup> The Pharmacy Contractor must oversee and keep a record to confirm that all staff have undertaken the training prior to participating in administration of the vaccination. This includes training for all vaccines recommended by the JCVI for use in the COVID-19 vaccination programme: phase 3 and any additional training associated with new vaccines that become available during the term of this LES Agreement;
- 12.3.5 have the necessary skills and training to administer vaccinations in general, including completion of the general immunisation training, for example that available on e-learning for health, and face-to-face administration training, where relevant;
- 12.3.6 the necessary skills and training, including training with regard to the recognition and initial treatment of anaphylaxis; and
- 12.3.7 be familiar with, understand and act within the scope of any Patient Group Direction or National Protocol for the COVID-19 vaccines.
- 12.4 The Pharmacy Contractor must ensure that relevant staff are appropriately trained in preparing vaccinations 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.
- 12.5 The Pharmacy Contractor must complete:

<sup>13</sup> <https://www.e-lfh.org.uk/>

12.5.1 [the clinical checklist for 16-17 year olds](#)<sup>14</sup> as soon as practicable after the Commencement Date of the LES and prior to vaccinating anyone in this age group; and

12.5.2 [the clinical checklist](#)<sup>15</sup> and confirmation of compliance with the [workforce considerations](#)<sup>16</sup> for 12 - 15 year olds as soon as practicable following receipt of notification from the Commissioner (NHSE) and prior to vaccinating anyone in this age group; or

12.5.3 [the clinical checklist](#)<sup>17</sup> and confirmation of compliance with the [workforce considerations](#)<sup>18</sup> for 5–16 year olds as soon as practicable following receipt of notification from the Commissioner (NHSE) and prior to vaccinating anyone in this age group.

12.6 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>19</sup>

12.7 Staff involved in the delivery of this LES Agreement must be familiar with and follow up-to-date [Infection Prevention and Control advice](#).<sup>20</sup> The Pharmacy Contractor must ensure that such persons understand what they should do if a Patient with symptoms of COVID-19 comes into the Designated Site where COVID-19 vaccination is being provided.

12.8 The Pharmacy Contractor must ensure that staff are appropriately trained and understand what their role in the delivery of this LES Agreement 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. The Pharmacy Contractor must also ensure that staff are made aware of the risks associated with the handling and disposal

<sup>14</sup> <https://future.nhs.uk/CovidVaccinations/view?objectId=122010373>

<sup>15</sup> <https://future.nhs.uk/CovidVaccinations/view?objectId=122010373>

<sup>16</sup> <https://future.nhs.uk/connect.ti/CovidVaccinations/view?objectId=108802789>

<sup>17</sup> <https://future.nhs.uk/CovidVaccinations/view?objectId=122010373>

<sup>18</sup> <https://future.nhs.uk/connect.ti/CovidVaccinations/view?objectId=108802789>

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

<sup>20</sup> <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control>

of clinical waste and that correct procedures are used to minimise those risks. A needle stick injury procedure must be in place.

12.9 The Pharmacy Contractor must ensure that:

12.9.1 staff involved in the administration of the vaccination to Patients are signposted to the following vaccinations:

12.9.1.1 Hepatitis B;

12.9.1.2 COVID-19; and

12.9.1.3 Seasonal influenza; and

12.9.2 all other staff involved in the delivery of this LES Agreement are signposted to the following vaccinations:

12.9.2.1 COVID-19; and

12.9.2.2 seasonal influenza.

## 13 Premises requirements

13.1 The Pharmacy Contractor will propose the location of the Designated Site, which shall be agreed with the Commissioner (NHSE) prior to commencement of the administration of vaccinations and in accordance with the Site Designation Process and where that Site demonstrates 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 (NHSE) through the designation process. It is envisaged that low volume sites will only be commissioned from Pharmacy premises. The Pharmacy Contractor shall not change the location of the Designated Site without the prior written agreement of the Commissioner (NHSE).

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.

13.3 Equipment that has been agreed with the National COVID-19 vaccination programme as reasonably required to set up a Designated Site will be

supplied to large and medium volume sites. It is envisaged that equipment will not be supplied to low volume sites, unless there are exceptional circumstances. Such equipment will remain the property of the Commissioner (NHSE) and must be secured and well maintained until such a time as it is returned to the Commissioner (NHSE).

- 13.4 Vaccinations administered in accordance with this LES Agreement must be administered at the Designated Site unless specific agreement is provided, in advance, by the Commissioner (NHSE) setting out the circumstances in which a vaccination can occur at a different location (for example, to improve vaccination uptake or to permit vaccination of specific Patient groups at alternative premises at given date(s) and/or time(s)).
- 13.5 Where the Patient is unable to access the Designated Site, the Pharmacy Contractor may agree in advance with the Commissioner (NHSE) that the Patient may be vaccinated in other suitable locations, such as in the Patient's home, a long-stay care home, or a long-stay residential facility.
- 13.6 Prior to service commencement and throughout the term of this LES Agreement, the Commissioner (NHSE) 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 LES Agreement or to ensure that the services are being delivered in accordance with this LES Agreement. The Commissioner (NHSE) may authorise other organisations to act on its behalf in undertaking such an assessment visit. The Pharmacy Contractor will be notified by the Commissioner (NHSE) in advance of any visit and the details of who will undertake that visit.
- 13.7 Vaccinations must only be offered where suitable facilities are available and Patient dignity and confidentiality can be respected. The minimum requirements are:
  - 13.7.1 the Designated Site (or associated premises where the Designated Site is not the registered pharmacy premises) must meet the GPhC premises standards;
  - 13.7.2 social distancing where required must be maintained before and after the vaccination has taken place;



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

13.7.4 it must be possible for infection prevention control standards to be maintained; and

13.7.5 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:

13.7.5.1 appropriate social distancing where required;

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

13.7.5.3 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.

13.8 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.

13.9 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.

13.10 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 offer vaccinations seven days a week, from 8am to 8pm, including on bank holidays or during appropriate hours across the week, to meet the needs of the local population as agreed

by the Commissioner (NHSE). Actual delivery hours shall be agreed with the Commissioner (NHSE) 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. 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.

14.2 Whilst pandemic regulations remain in place:

14.2.1 and where the Pharmacy Contractor wishes to provide vaccinations at their Pharmacy premises outside of usual opening hours, an application to limit the range of pharmaceutical services provided within those hours can be made by submitting a [Flexible Provision application](#)<sup>21</sup> to the Commissioner (NHSE) following the process in [section 9 of the Guidance](#),<sup>22</sup> and/or

14.2.2 in response to the omicron variant of the COVID-19 virus, the Commissioner (NHSE) requests that the Pharmacy Contractor considers applying to the Commissioner (NHSE) regional office to limit the pharmaceutical services they provide to enable further capacity to administer vaccinations, as permitted under Regulation 27B of the Pharmacy Regulations. This should be for up to twenty percent (20%) of a Pharmacy Contractor's combined weekly core and supplementary hours per week, or more with the prior written agreement of the Commissioner (NHSE). The Pharmacy Contractor can expect requests to be agreed by the Commissioner (NHSE) **between 16 December and 16 January** where:

14.2.2.1 the [Flexible Provision application](#) is attached to an email request and sent to the [e-mail address on the Commissioner \(NHSE\) website](#) with the subject header: "**Approval Request for Vaccination Site Flexible Provision**";

<sup>21</sup> <https://www.england.nhs.uk/primary-care/pharmacy/pharmacy-manual/pharmacy-application-forms/>

<sup>22</sup> <https://www.england.nhs.uk/publication/guidance-on-the-national-health-service-charges-and-pharmaceutical-and-local-pharmaceutical-services-amendment-regulations-2020/>

- 14.2.2.2 24 hours' notice is provided;
  - 14.2.2.3 the limitation of pharmaceutical services is at hours / days of the week that will have the least impact on patients;
  - 14.2.2.4 the application includes details of the Designated Site (ODS code and site name) and the name (and ODS code) of alternative community pharmacy premises which will provide support to any patients affected during the period when the Pharmacy Contractor is only open for COVID-19 vaccinations;
  - 14.2.2.5 the Pharmacy Contractor provides clear signposting to patients for alternative community pharmacy provision;
  - 14.2.2.6 the Pharmacy Contractor has in place a process to ensure that all patients retain access to their medicines, including provision of an emergency delivery service where necessary. An emergency delivery service will be funded in accordance with paragraph 15.6A from 15 December 2021 to 31 January 2022;
  - 14.2.2.7 all workforce released from other pharmaceutical services are actively involved in the delivery of COVID-19 vaccinations for the duration of time that the other pharmaceutical services are limited by the Pharmacy Contractor; and
  - 14.2.2.8 the Pharmacy Contractor ensures their Directory of Service (DoS) entry and NHS website profiles are accurate and reflect the times that a full range of Pharmaceutical Services will be offered so that patients can continue to be effectively signposted to appropriate services.
- 14.3 The Pharmacy Contractor must have business continuity plans, including ensuring appropriate availability of trained staff are in place to enable them to meet the agreed vaccination commitments while ensuring that safe staffing levels are maintained.
- 14.4 In the event that the Pharmacy Contractor needs to temporarily suspend the administration of vaccinations in accordance with this LES Agreement, this shall be agreed with the Commissioner (NHSE) and relevant changes must be made as soon as practicably possible to the National Booking Service.

- 14.5 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. Where there are necessary changes to planned appointments/clinics, the Pharmacy Contractor shall work with the Commissioner (NHSE) and shall communicate any such changes to relevant Patients.
- 14.6 Where a Pharmacy Contractor is unable to, or appears unlikely to meet the agreed vaccination volumes, the Commissioner (NHSE) may require the Pharmacy Contractor to provide, within the timescale determined by the Commissioner (NHSE), explanation and feedback. The Commissioner (NHSE) may by written notice to the Pharmacy Contractor terminate this LES Agreement immediately or on such notice as the Commissioner (NHSE) deems appropriate if the Commissioner (NHSE) is satisfied that the Pharmacy Contractor is no longer able to meet the requirements of this LES Agreement.

## 15 Payment arrangements<sup>23</sup>

- 15.1 Claims for Service Payments for this LES Agreement must be made by the 5<sup>th</sup> 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 six months following administration of the vaccination will not be processed and the Pharmacy Contractor will not receive any Service Payment for those vaccinations.
- 15.2 Service Payments will be made according to the FP34 Schedule of Payments. Claims will show on payment schedules under the 'COVID Vaccine' header.
- 15.3 The item of service payment is £12.58 per administration of a vaccination to each Patient except where paragraph 15.3A or 15.3B applies.
- 15.3A To support an increase in the number of vaccinations administered to Patients during December 2021 and January 2022, the item of service payment is

<sup>23</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=112344869](https://future.nhs.uk/P_C_N/view?objectId=112344869)

£15.00 per administration of a vaccination to each Patient where the vaccination is administered during the period 1 December 2021 to 31 January 2022 and where the administration of the vaccination occurs on a Monday to Saturday (but exclusive of 25 December 2021 to 3 January 2022); **or**

15.3B To support an increase in the number of vaccinations administered to Patients during Sundays and from 25 December 2021 to 3 January 2022, the item of service payment is £20.00 per administration of a vaccination to each Patient where the vaccination is administered during the period 1 December 2021 to 31 January 2022 and where the administration of the vaccination occurs on a Sunday or any day from 25 December 2021 to 3 January 2022. Pharmacy Contractors must not reschedule vaccinations or vaccination clinics for the purposes of receiving the Sunday payment as set out at this paragraph 15.3B. Pharmacy Contractors are required to maintain at least a broadly comparable vaccination clinic schedule, as was delivered prior to the 1 December 2021 and may provide additional Sunday clinics where this is necessary due to operational issues, staffing and to meet Patient demand. For the avoidance of doubt, rescheduled clinics for the purposes of receiving Sunday and any day from 25 December 2021 to 3 January 2022 payments, would not satisfy all relevant provisions of this LES Agreement and the Commissioner (NHSE) may determine to withhold payment.

15.4 Subject to compliance with this LES a supplement as set out at either paragraph 15.4.1, 15.4.2 or 15.4.3 (whichever is the greater) shall be payable to the Pharmacy Contractor (in addition to the item of service payment at either paragraph 15.3, 15.3A or 15.3B):

15.4.1 A supplement of £10.00 shall be payable for administration of each vaccination to each Patient where that Patient requires administration of a vaccination; and where the Community Pharmacy has recorded the status of the Patient in the Point of Care System prior to making the claim for payment; and:

- 1) where that Patient is:
  - i. resident in and receives the vaccination at a Care Home or residential setting (including care homes for people with learning disabilities or mental health problems, or hostel/hotel accommodation for the

homeless, where it would not be possible for these patients to attend vaccination sites); **or**

- ii. employed or engaged by a Care Home and receives the vaccination at that Care Home or residential setting; **or**
- iii. the medical condition of a Patient is such that, in the reasonable opinion of the **patient's registered** GP practice 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; **or**

2) where that Patient is:

- i. aged **12 – 15 years**; **and**
- ii. at increased risk of serious COVID-19 disease that includes those with the conditions listed in the Green Book, chapter 14a<sup>24</sup>; **or**
- iii. the Patient is the household contact of individuals (either adults or children) who are immunosuppressed; **or**

3) **where that Patient is:**

- i. **aged 5 – 11 years**; **or**

15.4.2 A supplement of £30.00 shall be payable to the Pharmacy Contractor during this period (in addition to the item of service payment at either paragraph 15.3, 15.3A or 15.3B above);

- 1) for administration of each vaccination to each Patient during the period 16 September 2021 to 31 December 2021 where:

- (i) the medical condition of a Patient is such that, in the reasonable opinion of the **patient's registered** GP practice 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; **and**
- (ii) where that Patient requires administration of a vaccination; **and**
- (iii) where the Community Pharmacy has recorded the status of the Patient in the Point of Care System prior to making the claim for payment.

Where a smaller supplement has been paid in respect of this group of Patients, this shall be increased to the total supplement of £30.00. The total supplement in this regard shall not exceed £30.00 for the administration of each vaccination to Patients in this group; **or**

15.4.3 £10.00 shall be payable to the Pharmacy Contractor (in addition to the item of service payment at either paragraph 15.3, 15.3A or 15.3B above);

1) for administration of each vaccination to each Patient during the period 1 December 2021 to 31 March 2022 where:

- (i) the Patient was severely immunosuppressed in proximity to previous vaccination due to underlying health condition or medical treatment as defined by JCVI on 1 September 2021<sup>25</sup> or the Green Book.
- (ii) where that Patient requires administration of a vaccination; **and**

<sup>25</sup> <https://www.gov.uk/government/publications/third-primary-covid-19-vaccine-dose-for-people-who-are-immunosuppressed-jcvi-advice/joint-committee-on-vaccination-and-immunisation-jcvi-advice-on-third-primary-dose-vaccination>

- (iii) where the Community Pharmacy has recorded the status of the Patient in the Point of Care System prior to making the claim for payment; **and**

- 15.4A For the avoidance of doubt, where a Patient qualifies for more than one supplementary payment in respect of the administration of the vaccination to a Patient, the highest cost supplement shall be paid to the Pharmacy Contractor only.
- 15.5 The vaccines made available under this LES Agreement will be provided to the Pharmacy Contractor free of charge, and therefore no reimbursement of the cost of the vaccine is payable.
- 15.6 Funding for additional reasonable costs may be available from the Commissioner (NHSE) where the Pharmacy Contractor meets the requirements of the Financial and Payments Guidance for NHS Regional Teams, available on NHS Futures. Pharmacy Contractors must seek pre-authorisation from the Commissioner (NHSE) before incurring any costs that they intend to claim and provide associated evidence or invoices within four weeks of pre-authorisation.
- 15.6A Where the Pharmacy Contractor applies to the Commissioner (NHSE) to limit the pharmaceutical services in accordance with paragraph 14.2.2 of this LES Agreement and the Commissioner (NHSE) agrees, then the Pharmacy Contractor shall be permitted to claim £6.00 (including VAT) for each delivery of medicines. This payment can only be claimed where the:



- i) delivery is to supply medicines or appliances dispensed against a prescription;
- ii) delivery is made during hours when the Pharmacy Contractor has limited their usual Pharmaceutical Services to COVID-19 and influenza vaccinations only; and
- iii) patient would ordinarily have collected the medication from the pharmacy during hours when the Pharmacy Contractor has limited their usual Pharmaceutical Services to COVID-19 and influenza vaccinations only;
- iv) medicines are urgently required by the patient prior to the Pharmacy Contractor resuming the pharmaceutical services; and
- v) delivery is made within the period from 15 December 2021 to 31 January 2022;

15.6B To improve equality of access and support an increase in the number of vaccinations administered to Patients, an exceptional supplement totalling £500 will be paid in addition to the fees set out in paragraph 15.3 and paragraph 15.4 for each clinic administering vaccinations at the request of the Commissioner (NHSE) between 15 January 2022 and 31 January 2022.

This payment can only be claimed where:

- i) all un-booked capacity from an existing clinic is open to Patients without an appointment (“walk-in clinic”) for not less than four hours per clinic, per day; and
- ii) the Pharmacy Contractor complies with any publication / advertising requirements of the Commissioner (NHSE); and
- iii) workforce at the site are NOT drawn from those supplied free of charge to the Pharmacy Contractor; and
- iv) the claim is for a maximum of one clinic per day.

15.6C To improve equality of access for eligible Patients aged under 12 years, an exceptional supplement totalling **£1500** (including VAT) shall be payable to

the Pharmacy Contractor in addition to the fees set out in paragraph 15.3 and paragraph 15.4 where a Pharmacy Contractor:

- i) complied with the provisions at 12.5.2 and/or 12.5.3 (as relevant) and returned information to the regional team before 30 April 2022;
- ii) has received notice in writing from the Commissioner (NHSE) that they may vaccinate those eligible Patients under 12 years of age;
- iii) will continue to deliver the vaccinations to those aged under 12 years until the end of the term of the LES except where a shorter term is agreed with the Commissioner (NHSE).

15.7 Claims submitted in accordance with this LES Agreement will only be paid where:

- vi) the Patient was within one of the eligible JCVI Cohorts and that JCVI cohort was announced and authorised by the Commissioner (NHSE) at the time the vaccine was administered or there were exceptional circumstances as set out at paragraph 4.6;
- vii) a vaccine recommended in the relevant guidance was used;
- viii) the administration of the vaccination has been recorded on the specified Point of Care System;
- ix) 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 (NHSE) relating to the delivery of the COVID-19 vaccination programme) in respect of the vaccine or vaccination; and
- x) the claim for payment was submitted in accordance with paragraph 15.1.

15.8 If the Pharmacy Contractor does not satisfy all relevant provisions of this LES Agreement, the Commissioner may determine to withhold payment of all, or part of, an amount due under this LES Agreement that is otherwise payable.

15.9 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 LES Agreement.

15.10 If the Commissioner (NHSE) makes a payment to a Pharmacy Contractor under this LES Agreement and:

- i) 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; or
- ii) the Commissioner (NHSE) 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
- iii) the Commissioner (NHSE) is entitled to repayment of all or part of the money paid,

the Commissioner (NHSE) 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 LES Agreement that the contractor must pay to the Commissioner (NHSE) that equivalent amount.

- b) 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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