

Community Pharmacy Local Enhanced Service – Coronavirus Vaccination

COVID-19 vaccination programme 2020/21



**Community Pharmacy Local Enhanced Service description – Coronavirus
Vaccination 2020/21**

Version number: FINAL

First published: December 2020

Prepared by NHS England and NHS Improvement

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 securing that services are provided in an integrated way where this might reduce health inequalities."

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Introduction

As of December 2020, several potential vaccines for COVID-19 are in the later stages of phase III trials. Some of these are being authorised for use following trials and testing and the NHS has commenced its COVID-19 vaccination programme.

The NHS is a global leader in achieving high levels of vaccination coverage. The UK has one of the world's highest levels of public support for making a safe COVID-19 vaccine available. Community pharmacy is currently doing an outstanding job of increasing coverage under the expanded winter flu programme. Through their place in local neighbourhoods, pharmacies are well placed to reach out to our diverse communities and avoid inequalities in access. This means community pharmacy has an important role in the COVID-19 vaccination programme, alongside other providers.

We are commissioning an [Enhanced Service from general practice](#). That service invited general practices to nominate premises in their Primary Care Network grouping where vaccines are to be administered to their combined population. Community pharmacy contractors are encouraged to discuss collaboration with their local Primary Care Network to support them to deliver maximum vaccine uptake. This may be, for example, by professional staff overseeing vaccination or by providing vaccines to residents and staff of care homes. Such a collaboration agreement would be between the Primary Care Network and the Pharmacy Contractor and would fall outside this service agreement.

This agreement document sets out the detail of how NHS England and NHS Improvement will commission a COVID-19 vaccination service directly from community pharmacy. It will be commissioned where there is a local need, for example where there is a gap in service provision or need for additional capacity, and where Pharmacy Contractors can meet the key designation requirements. The service will be provided as a Local Enhanced Service (LES), commissioned by NHS England and NHS Improvement regional teams in consultation with Local Pharmaceutical Committees.

This LES agreement relates to COVID-19 vaccinations only.

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

Commonly used terms

Commissioner (NHS England & NHS Improvement) – the NHS Commissioning Board, responsible for direct commissioning of pharmaceutical services

Designation Process – the process whereby Pharmacy Contractors are able to nominate a site for the service to take place and NHS England and NHS Improvement can select premises to address service provision gaps

Designated Site - a site selected as part of the Designation Process

GPhC - the General Pharmaceutical Council

Local Enhanced Service (LES) - this Coronavirus Vaccination local enhanced service

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 the Patient can book appointments for their COVID-19 vaccinations.

State indemnity - arrangements that provide clinical negligence indemnity cover as specified for all staff engaged by a Community Pharmacy Contractor in the delivery of services under this LES. This indemnity provides cover for activities undertaken as part of this LES only and as set out in the letter of indemnity sent to Designated Contractors. State indemnity is provided until 31 March 2021 and afterwards a risk sharing arrangement will be adopted.

Agreement between the parties

Commissioner	NHS England and NHS Improvement [Insert contact details for NHSEI regional team]
Provider	[Insert pharmacy name and address]
Enhanced services to be provided (“the Local Enhanced Service”)	Coronavirus Vaccination Service
Commencement Date	[Insert local enhanced service commencement date]
End date	31 August 2021, or until any of the following occur and this service automatically ceases (whichever is the sooner): <ul style="list-style-type: none"> the COVID-19 Vaccination Programme comes to an end; the Commissioner determines that there is no requirement for mass COVID-19 vaccinations to be delivered by the Provider; there is no need for vaccinations for the specified population; State indemnity is no longer available (after 31 March 2021) and the contractor is unable to source other suitable indemnity provision.
Review date	[Insert review date, if there is one]
Service Payment	£ 12.58 per vaccination given (where vaccination conditions as set out in section 14 of the service description are met) See section 14 of the service description attached which sets out what the payment covers and how to submit claims

This service is an enhanced service as defined in The Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013. It is subject to the terms set out below.

Enhanced service terms

- 1.1 The Pharmacy Contractor agrees to provide the Local Enhanced Service from the Commencement Date until the End Date, unless terminated earlier in accordance with these terms.
- 1.2 The Pharmacy Contractor shall provide the Enhanced Service in accordance with these terms 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 Local Enhanced Service as an opportunity to attempt to influence a Patient's choice of pharmacy for other Pharmaceutical Services, 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 shall provide the Enhanced Service fully in accordance with the service description attached to this LES.
- 1.5 In consideration of the Pharmacy Contractor's provision of the Local Enhanced Service in accordance with these terms, the Commissioner agrees to pay the Service Payment to the Pharmacy Contractor as set out in the table above and at Section 13 of the attached service description.
- 1.6 Termination provisions:
 - 1.6.1 The Pharmacy Contractor may terminate this Enhanced Service by serving not less than six weeks' (42 days) written notice on the Commissioner at the address set out above. The Commissioner may, at their discretion agree a shorter notice period where they are able to commission an alternative provider. Where, due to an emergency the Pharmacy Contractor is not able to provide this notice period, they should contact the Commissioner to agree an amended timeframe with them;
 - 1.6.2 The Commissioner may terminate this Local Enhanced Service by serving not less than 42 days' notice on the Pharmacy Contractor at the address set out above;

- 1.6.3 This Enhanced Service shall terminate automatically on termination of the Pharmacy Contractor’s LPS contract, or removal of the Pharmacy Contractor from the Pharmaceutical List, in relation to the pharmacy at which it provides the Enhanced Service.
- 1.7 This LES is specific to the Pharmacy Contractor and the Pharmacy Contractor may not assign, novate or otherwise seek to transfer any of its rights or obligations under this LES to any other party without the specific written permission of the Commissioner.
- 1.8 Except where it is expressly stated to the contrary, this LES does not give rise to any rights enforceable by any person who is not a party to it.
- 1.9 The Pharmacy Contractor agrees to these Local Enhanced Service terms by either signing and returning a physical or digitally completed agreement as below.
- 1.10 If the agreed period of the LES is to be extended, the Commissioner will notify the Pharmacy Contractors of the extension period and agree via email or verbally the extension with each Pharmacy Contractor.
- 1.11 Pharmacy Contractors may, at that point of extension, notify the Commissioner that they do not wish to continue to provide the service past their previously agreed service termination date.
- 1.12 In recognition of uncertainties in obtaining indemnity provision for these novel vaccines, state indemnity covering clinical negligence will be provided to those working under the terms of this LES until 31 March 2021 by way of a separate offer letter and only as detailed in that letter. Annex A provides further information.

Signed for and on behalf of the Commissioner:

Signature

Name

Job title

Classification: OFFICIAL SENSITIVE

Signed for and on behalf of the Pharmacy Contractor:

Signature

Name

Job title

Service Description

1 Service description and background

A COVID-19 Vaccination Programme has been established to enable the safe administration of COVID-19 vaccinations to adults in England.

Vaccinations will be provided to eligible cohorts from a variety of providers, who will be required to administer at least 1000 doses of vaccine each week, in a way that minimises waste, and makes best use of available supply.

Provision of the service must comply with the [Standard Operating Procedure: COVID-19 local vaccination services deployment in community settings](#) and which may be updated from time to time.

This description is intended to detail the requirements of the service that can be commissioned from Community Pharmacy Contractors by Commissioners. It may be subject to amendment from time to time as the vaccination programme develops.

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. The commencement date for vaccine delivery will not be less than 7 calendar days from the written notification.

2 Aims and intended outcomes

The aims of this service are:

- to maximise uptake of COVID-19 vaccine in identified [at risk groups](#)¹ by using Community Pharmacy Contractors to supplement service provision by general practice Primary Care Networks (PCNs) in local vaccination services or through larger vaccination centres where a need is identified by regional Commissioners;

¹ <https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-2-december-2020>

- to increase opportunities for specified cohorts of patients to access COVID-19 vaccinations and/or improve convenience and choice; and
- to ensure that vaccination services can be provided in a variety of settings and using staff from across primary care.

3 Patient cohorts and priority groups

3.1 The Pharmacy Contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible patient shall be excluded or experience particular difficulty in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.

3.2 Patients will be offered a vaccination in priority order (see 'Eligible patients' below) as vaccine becomes available. The Commissioner will announce the authorisation of cohorts for vaccination. These cohorts are subject to change (including consolidation, expansion and reprioritisation) – such changes will be published on <https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation> and contractors will be notified by NHS England and NHS Improvement of amendments through our [Primary Care Bulletin](#).

3.3 Pharmacy Contractors must be prepared to provide COVID-19 vaccination to any patient in the authorised cohorts, in priority order; unless contraindicated. Patients in unannounced cohorts are not eligible to be vaccinated under this service until that announcement has been made in relation to their cohort.

4 Eligible patients

4.1 Patients who have booked appointments with the National Booking Service (NBS) will have eligibility confirmed prior to booking..

4.2 Below is an indicative list of the cohorts that form part of this description and which will become eligible for vaccination under this LES. It is subject to amendment or addition over time. A Ministerial Decision, based on guidance from JCVI, will identify priority cohorts and the order in which eligible adult cohorts come onstream.

- i. Residents in a care home for older adults and their carers
- ii. All those 80 years of age (and over) and frontline Health and Social Care Workers
- iii. All those 75 years of age and over
- iv. All those 70 years of age and over and clinically extremely vulnerable individuals
- v. All those 65 years of age and over
- vi. All individuals aged 16-64 years with underlying health conditions which put them at higher risk of serious disease and mortality
- vii. All those 60 years of age and over
- viii. All those 55 years of age and over
- ix. All those 50 years of age and over

4.3 Pharmacy Contractors must only administer vaccinations to patients who have been offered a vaccination through the national call / recall service.

5 Patient recruitment

5.1 When patients are offered a vaccination by the national call/recall system they will be invited to make an appointment at a PCN general practice led site or use the National Booking Service (NBS) to be vaccinated by another provider such as a community pharmacy.

5.2 Contractors will not be eligible for payment for the administration of vaccinations outside the announced authorised cohorts unless otherwise agreed in writing with the Commissioner.

5.3 Contractors 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 Assessment and consent

6.1 A registered healthcare professional, trained in vaccine administration, and familiar with the characteristics of the vaccine being administered, must assess 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.

6.2 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.

6.3 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 and NHS Improvement (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.

6.4 Each patient being administered a vaccine must be given written information about the vaccine as specified by Public Health England². 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 Vaccine administration

7.1 Pharmacy contractors must ensure that vaccinations offered under this service are provided in line with guidance in Immunisation against infectious disease ([The Green Book](#))¹, including relevant details on the treatment of anaphylaxis and disposal of clinical waste.

7.2 Pharmacy Contractors must follow guidance published by the JCVI and/or Public Health England on:

² <https://www.gov.uk/government/collections/covid-19-vaccination-programme>

- which vaccine is the most suitable for each cohort;
- handling and manipulation of the vaccine by healthcare professionals with the appropriate skills to do so;
- the relevant maximum and minimum timescales for administration of each vaccine;
- the number of doses of each vaccine required to achieve the desired immune response;
- the required gap between doses of each vaccine; and
- any other relevant guidance relating to the administration of the different types of vaccine and the different cohorts from time to time.

This guidance is subject to change as the vaccination programme develops.

7.3 Where the vaccine is part of a multi-dose regimen, the contractor must ensure the Patient receives the correct dosage of the vaccine as is clinically appropriate and has understood that failure to receive all doses may render vaccination ineffective. They should encourage the Patient to make or attend a follow up appointment to receive the subsequent dose(s). The Patient should receive all doses in the regimen from the same provider unless, in exceptional circumstances (see 7.4 below), the provider of previous doses is unable to complete the regimen.

Exceptional circumstances criteria and process

7.4 There may be exceptional circumstances where a Pharmacy Contractor should be paid for the administration of a single dose of the vaccine which are that:

- The vaccine is no longer suitable for the Patient because:
 - Medicine intolerance or allergy was discovered during administration of the first dose;
 - The Patient has commenced end of life care before a second dose of the vaccine could be provided;
 - the Patient has died before a second dose could be provided; or
 - The full course of the vaccine is a single dose.
- The Patient's circumstances have changed because:
 - the Pharmacy Contractor has not been provided with the vaccine in order for the Pharmacy Contractor to administer the vaccination within the recommended time frame.
 - The Patient has definitively chosen not to receive the second dose of the vaccine following a discussion with a clinician;

- The patient has moved residence and/or has declined to receive subsequent doses from the first provider.
- The patient has not attended a booked appointment and the pharmacy contractor has attempted contact with the Patient on at least two separate occasions within a week of the appointment.

7.5 The Pharmacy Contractor must make proactive attempts on at least two separate occasions to contact patients who have failed to attend or cancelled subsequent appointments and support them in booking a further appointment if appropriate. The date and times of attempted contacts must be recorded.

7.6 A record must be made if the Patient receives a part course due to a qualifying exception or where the Contractor could not contact the Patient to support a payment claim.

8 Vaccine handling and storage

8.1 Vaccines offered under this service 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 NHS England and NHS Improvement's instructions and associated Standard Operating Procedures. Receipt, storage and preparation of vaccines used under this service should also be undertaken with appropriate clinical oversight and with regard to governance arrangements in place for the service.

8.2 Contractors must agree with the Commissioner as part of the site Designation Process the number of vaccinations they can deliver each week. A minimum of 1000 vaccinations each week is required as set out in the original Site Designation documents.

8.3 On a regular basis (at least weekly) Contractors will need to agree the number of vaccines they will deliver. Where vaccination supply allows, this should be a minimum of 1000 vaccines per week as agreed as part of the site Designation Process.

8.4 At the sole discretion of the Commissioner, Contractors may be authorised to provide fewer than 1000 vaccines per week for a predetermined period to allow them to vaccinate specific patient groups where it is already known that 1000 vaccines will not be needed or possible within that week (eg vaccination of rough sleepers in a given area over a given number of days). Contractors will only receive payment for the actual number of vaccines administered.

8.5 Vaccinations will be centrally supplied and are expected to be delivered by pharmacy wholesalers. Other consumables and items required to allow for vaccinations to take place will be supplied in line with the Supply Inventory List (published at <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/equipment-and-consumables-provision-and-supply/>).

8.6 All vaccines must be stored in accordance with the manufacturer's instructions and all relevant NHS England and NHS Improvement SOPs. All refrigerators in which vaccines are stored are required to have a maximum / minimum thermometer so that vaccines can be stored between 2-8°C. Readings are to be taken and recorded from the thermometer on all working days. Where vaccinations are approved by the Commissioner to be undertaken outside General Pharmaceutical Council (GPhC) registered pharmacy premises, the pharmacy contractor must continue to ensure that appropriate measures are taken to ensure the integrity of the cold chain as well as meeting other GPhC standards.

8.7 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. Wastage levels will be reviewed by the Commissioner on an ongoing basis.

9 Record keeping

9.1 Contractors must adhere to defined standards of record keeping ensuring that the vaccination event is recorded the same day that it is administered within the specified point of care clinical system in line with relevant guidance. Contractors must ensure that any staff recording the vaccination have received the relevant training to be able to update records appropriately.

9.2 The Pharmacy Contractor must maintain appropriate records to ensure effective ongoing service delivery.

9.3 Access to an on-line digital system for making records of vaccinations will be provided. Clinical records must be made on the system as soon as reasonably possible after the vaccination is administered, and before the end of the same day that the vaccination was administered. Any staff recording information must have received relevant training to allow them to update records.

9.4 Where the digital system is unavailable due to circumstances beyond the control of the Contractor, then the records must be added to the system as soon as possible after the

system becomes available again. The Commissioner must be notified if this will result in records of vaccinations being added on a different day than administration occurred.

9.5 The digital 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.

9.6 Automated activity information will be reported daily and will include a count of all eligible patients who received a COVID-19 vaccination that day. Contractor's may be required to provide manually downloaded reports if automated reporting is unavailable or fails. This information will be used by NHS England and NHS Improvement and Public Health England for forecasting ongoing vaccine requirements, monitoring uptake and national reporting.

10 Governance and accountability

10.1 Pharmacy Contractors providing services under this LES must (if they have not already done so) sign up to receive the NHS England and NHS Improvement Primary Care Bulletin so that key information in relation to the delivery of this service can be communicated in a timely manner. Contractors can sign up to the Bulletin at:

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

10.2 There is an expectation that this Service will operate as part of the wider NHS system in providing COVID vaccinations, and Contractors should work with specialist pharmacy colleagues and the Specialist Pharmacy Services (SPS) to obtain advice and guidance where necessary.

10.3 Pharmacy Contractors should name a clinical lead for this LES within their organisation/pharmacy. That lead should be a pharmacist, registered with the General Pharmaceutical Council (GPhC), and trained in vaccinations (including having a clear understanding of the requirements of this Service). They will be the lead contact for this service for contractual and professional matters.

10.4 Each Designated Site should operate under the supervision of a pharmacist, registered with the General Pharmaceutical Council, trained in vaccinations (including a clear understanding of this Service). A record should be maintained of who that person is

at each site at any given time. The Responsible Pharmacist at the registered pharmacy premises (or associated premises if the Designated Site is not the registered pharmacy) is professionally responsible for the safe delivery of this Service.

10.5 Any Pharmacy Professional involved in the provision of services under this LES (whether delivering vaccinations directly or supervising others providing vaccinations) must adhere to all professional standards, no matter what the setting. Information on what is expected of pharmacy professionals working under this LES is available on the GPhC website: <https://www.pharmacyregulation.org/standards/guidance/ga-coronavirus/covid-19-vaccination-programme>

10.6 Pharmacy Contractors should ensure that this service, and all clinical professionals and other staff working within it are covered by appropriate indemnity. State indemnity arrangements provide the specified clinical negligence indemnity cover for all staff engaged by a Pharmacy Contractor in the delivery of services under this LES until 31 March 2021 by way of a separate letter of indemnity. However, Pharmacy Contractors must also ensure they have adequate commercial insurance in place to cover other liabilities (e.g. public and employers). Access to medico legal advice and support remains an individual matter for pharmacists and other registered healthcare professionals involved in delivering the LES.

10.7 Pharmacy Contractors are responsible for ensuring that all staff are trained as appropriate to their role within this service (see section 11 Training) and that those staff are aware of the contents of the relevant Patient Group Direction or National Protocol that covers the vaccinations delivered under this Service.

10.8 Where a Patient experiences an adverse drug reaction or presents with an adverse drug reaction following the vaccination and the pharmacist 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](#)'³ report submitted. The incident reporting process available [here](#) must be followed.

10.9 The Pharmacy Contractor is required to report any patient safety incidents in line with local governance processes and in accordance with the clinical governance requirements of the [Community Pharmacy Contractual Framework](#).⁴

³ <https://yellowcard.mhra.gov.uk/>

⁴ <https://www.legislation.gov.uk/ukxi/2013/349/schedule/4/paragraph/28>

11 Training

11.1 Vaccines must be administered by an appropriately trained member of staff authorised under the [Public Health England Patient Group Directions or National Protocols](#)⁵.

11.2 Pharmacy Contractors must retain records that demonstrate that, prior to participating in vaccination (whether vaccinating patients themselves or supervising persons administering vaccines), all registered health professionals have:

- read and understood the clinical guidance as described in the Local Vaccination Services Standard Operating Procedure and
- be aware of the specific handling requirements and MHRA conditions associated with each of the vaccines being used under this Local Enhanced Service; and
- completed the COVID-19 vaccine specific training modules available on the [e-learning for health](#)⁶ website;
- the necessary experience, skills and training to store, 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; and
- the necessary experience, skills and training, including training with regard to the recognition and initial treatment of anaphylaxis; and
- be familiar with and understand the Patient Group Direction for the COVID-19 vaccines, made available by PHE and authorised by NHS England and NHS Improvement and or be familiar with a National Protocol for administration of any COVID-19 vaccination supplied and administered.

11.3 Contractors must also retain records that demonstrate that, prior to participating in vaccination, all other persons administering the vaccine must:

- be legally authorised under the terms of the [The Human Medicines \(Coronavirus and Influenza\) \(Amendment\) Regulations 2020](#)⁷; and
- while preparing and/or administering vaccinations be supervised by a healthcare professional fulfilling the requirements described above; and
- be aware of the specific handling requirements of each of the vaccines being used under this Local Enhanced Service; and

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

⁶ <https://www.e-lfh.org.uk/>

⁷ <https://www.legislation.gov.uk/uksi/2020/1125/contents/made>

- have completed the COVID-19 vaccine specific training modules available on the [e-learning for health](#)⁸ website. Contractors 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 any additional training associated with new vaccines that become available during the period of this Local Enhanced Service; and
- have the necessary skills and training to administer vaccines 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; and
- the necessary skills and training, including training with regard to the recognition and initial treatment of anaphylaxis; and
- be familiar with, understand and act within the scope of any Patient Group Direction or National Protocol for the COVID-19 vaccines.

11.4 The 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.

11.5 Staff participating in the service must be familiar with and follow up-to-date [Infection Prevention and Control advice](#).⁹ They must also understand what they should do if a patient with symptoms of COVID-19 comes into the pharmacy or other Designated Site where COVID-19 vaccination is being provided, as described in the [COVID-19 community pharmacy standard operating procedure](#)¹⁰.

11.6 The Pharmacy Contractor must ensure that staff are appropriately trained and understand what their role in the vaccination service entails, including working within the relevant systems and processes set out by the Contractor, and understanding how to report concerns should any be identified. The Contractor must also 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.

⁸ <https://www.e-lfh.org.uk/>
⁹

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/918091/IP_C_Highlights_Quick_Reference_Guide.pdf#:~:text=IPC%20Highlights%20Quick%20Reference%20Guide%20This%20guide%20sets,independent%20sector%20and%20supersedes%20all%20existing%20COVID-19%20guidance.

¹⁰ <https://www.england.nhs.uk/coronavirus/wp-content/uploads/sites/52/2020/03/C0796-covid-19-community-pharmacy-sop-v4.pdf>

11.7 The pharmacy contractor must ensure that they offer Hepatitis B vaccination to staff involved in the provision of this service and be advised of the risks should they decide not to be vaccinated. It is best practice to also vaccinate against COVID-19 and seasonal influenza.

12 Premises requirements

12.1 Throughout the duration of this LES, the Commissioner is entitled to access and inspect the Designated Site to ensure that the service is being delivered in line with the terms of this LES. The Commissioner may authorise other organisations to act on its behalf in undertaking these inspection visits. Contractors will be notified by the Commissioner in advance of any visit and the details of who will undertake that visit.

12.2 Prior to service commencement, the Commissioner is entitled to access and inspect the Designated Site to undertake an assessment of the site/Contractor's readiness to provide the service. The Commissioner may authorise other organisations to act on its behalf in undertaking such an assessment visit. Pharmacy Contractors will be notified by the Commissioner in advance of any visit and the details of who will undertake that visit.

12.3 Vaccinations under this service must be carried out at the Designated Site agreed with the Commissioner. Where the Patient is unable to access that site, the Pharmacy Contractor may agree in advance with the Commissioner that the Patient(s) 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.

12.4 Vaccinations must only be offered where suitable facilities are available and patient dignity and confidentiality is able to be respected. The minimum requirements are:

- Registered pharmacy premises (or associated premises where the Designated Site is not the main pharmacy premises) must meet the GPhC premises standards, including the requirements of 12.5 below
- Social distancing must be maintained before and after the vaccination has taken place
- The area where vaccines are administered must be distinct from the general public areas
- It must be possible for infection prevention control standards to be maintained
- There is a suitable area where patients can be observed for 15 minutes after vaccination if necessary (see the relevant vaccine PGD / National Protocol). This area must have: appropriate social distancing; access to appropriate equipment

such as adrenaline/anaphylaxis kits; and 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.

12.5 Where vaccinations are undertaken off the pharmacy premises, the Pharmacy Contractor must: follow any handling or storage requirements specific to the vaccine being administered; ensure that vaccinators have appropriate indemnity cover for off-site vaccinations; continue to adhere to all professional standards relating to vaccinations; follow appropriate cold-chain storage measures; ensure that the setting used to administer the vaccinations is appropriate (including ensuring patient confidentiality as appropriate and that the Patient can be monitored for 15 minutes post vaccination, where required); appropriately dispose of any clinical waste or personal protective equipment used during the vaccination process.

12.6 Additionally, where vaccinations are undertaken in the Patient's own home (including a care home), Pharmacy Contractors must ensure that vaccinators have a Disclosure & Barring Service (DBS) certificate.

12.7 The Pharmacy Contractor is required to comply with reasonable requests from the Commissioner or waste disposal company to facilitate the 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).

13 Service availability

13.1 Service provision should be as agreed as part of meeting the designation criteria for this LES. Pharmacy Contractors may be required, if needed, to offer this service for seven days a week, from 8am to 8pm, including on bank holidays, as agreed as part of becoming a Designated Site. No permanent changes to the Designated Premises or hours of service provision can be implemented without the agreement of the Commissioner.

13.2 The Pharmacy Contractor must have business continuity plans in place to enable them to meet the agreed minimum weekly vaccine commitments whilst ensuring that safe staffing levels are maintained. The Pharmacy Contractor should ensure that locums, relief pharmacists, and other staff are adequately trained, so as to ensure continuity of service provision throughout the full opening hours. See also section 10 'Governance and accountability' in relation to those engaged in provision of the Service.

13.3 If the Pharmacy Contractor temporarily or permanently ceases to provide the service, they must inform the national booking service to suspend bookings. The Commissioner of the service must also be notified as soon as is practicable to allow for local communication to other providers as necessary.

13.4 Where a Pharmacy Contractor's Designated Site is unable to, or appears unlikely to meet minimum vaccine volumes, the Commissioner may seek explanation and feedback, and may choose to withdraw this Local Enhanced Service if they are satisfied the Pharmacy Contractor is no longer able to meet the requirements of the service.

13.5 Pharmacy Contractors will be required to co-ordinate with the regional / STP operations centre to plan appointments / clinics according to expected vaccine supply and amend those schedules if there is a disruption to supply. They will also be required to undertake timely communication of any such changes to patients.

14 Payment arrangements

14.1 Claims for payments for this service should be made each month via the Manage Your Service (MYS) platform provided by the NHS Business Services Authority. Claims will show on payment schedules under the 'COVID Vaccine' header.

14.2 A payment of £25.16 shall be payable to the Pharmacy Contractor upon completion of the second administration of the vaccination to each Patient, where applicable. This £25.16 is made up of two service payments of £12.58 each and is intended to reflect the two vaccinations per patient which make up the course of the treatment. Payment of £12.58 will however be available for single administration of the vaccination in the exceptional circumstances set out at paragraph 7.4, or where the Patient has failed to attend a scheduled appointment for a second dose of the vaccination and the Pharmacy Contractor has evidence that they have attempted to contact them in line with the requirements of paragraph 7.5.

Exceptional circumstances criteria and process

14.3 The vaccines available under this service will be provided to the Pharmacy Contractor free of charge, and therefore no reimbursement of the cost of the vaccine is payable.

14.4 Claims submitted against this service will only be paid where:

- The Patient was within one of the eligible patient cohort groups at the time the vaccine was administered;
- A vaccine recommended in the relevant guidance was used;
- The vaccine has been recorded on the specified online point of care system;
- The Pharmacy Contractor did not receive and did not expect to receive any payment from any other source in respect of the vaccine.

14.5 Payment for a single dose can only be claimed if there is a record made of:

- The Patient having met a qualifying exception (as detailed at paragraph 7.4) and, if it was a Patient decision not to have further doses, that 28 days have passed since the decision was recorded; or
- the proactive attempts made by the Pharmacy Contractor on at least two separate occasions to contact and recall the Patient, and 28 days has passed since the last attempted contact.

14.6 If the Pharmacy Contractor does not satisfy the conditions of this Local Enhanced Service, Commissioners may, following Local Dispute Resolution, determine to withhold payment of all, or part of, an amount due under this service that is otherwise payable.

14.7 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 service. Where any claims are found to have been made incorrectly these may be subject to clawback where Local Dispute Resolution processes have been followed and the Pharmacy Contractor cannot evidence the claim is eligible for payment under this LES.

Annex A:

1. The Secretary of State for Health and Social Care (the “Secretary of State”) has a statutory duty to take steps to protect the public in England from disease, including by provision of vaccines, under section 2A of the National Health Service Act 2006 (the “Act”). Under Part 4 of the Pharmaceutical Services (Advanced and Enhanced Services) (England) Directions 2013 (as amended), given under section 127 of the Act, the Secretary of State has authorised the Commissioner to arrange for the provision of the Local Enhanced Service.
2. This LES, together with the relevant directions issued by the Secretary of State, authorises the Provider to arrange for the provision of the Local Enhanced Service.
3. This LES constitutes an entrustment (within the meaning of the SGEI Decision) from the Commissioner to the Provider to provide the Local Enhanced Service.
4. The State indemnity provided under this LES (at its date) is made under a separate letter of indemnity in compliance with the requirements set out in the SGEI Decision concerning public service compensation granted for Services in the General Economic Interest.”
5. For the purpose of this Annex and the LES the words and phrases listed below are given the following meanings:

“Legislation” – means:

- (a) any Act of Parliament;
- (b) any subordinate legislation within the meaning of Section 21(1) of the Interpretation Act 1978;
- (c) any exercise of the Royal Prerogative;
- (d) any enforceable EU right within the meaning of Section 2 of the European Communities Act 1972; in each case in the United Kingdom; and
- (e) any regulations, orders, bye-laws or codes of practice of any local or statutory or United Kingdom Competent Authority having jurisdiction over the territory in which the Provider is situated.

“Public Sector Subsidy” – means indemnification or subsidy towards indemnification relating to the administration of COVID-19 vaccinations (including the State indemnity) received or receivable by the Provider from public sector bodies including for this purpose funding from the European Commission, government bodies (whether national or local) or bodies in receipt of lottery funds from the National Lottery Distribution Fund pursuant to the National Lotteries Acts 1993 and 1998 and any further relevant indemnification provided by the Commissioner not provided under this LES;

“SGEI Decision” – means the European Commission's Decision on Services of General Economic Interest dated 20 December 2011 (2012/21/EU)

“SGEI Decision Overpayment” – means the extent to which the aggregate payment made under the State indemnity to the Provider exceeds the SGEI Decision Net Costs

“SGEI Decision Net Costs” means under the SGEI Decision the maximum amount of aid which may be provided without Unlawful State Aid arising

“SGEI Information” – means such information about or relating to the payment of the State indemnity and such other information as the Commissioner may reasonably request

“SGEI Review” – means a review by the Commissioner of the provision of the State indemnity to determine whether an SGEI Decision Overpayment has arisen

“State Aid” – means (as the case may be):

- (a) any aid granted by a Member State of the European Union or through the resources of such Member State in any form whatsoever which distorts or threatens to distort competition by favouring a particular undertaking or the production of certain goods, in so far as such aid affects trade between European Union Member States; or
- (b) any aid benefit or advantage (which includes but is not limited to assets, rates, funds and land) granted by or through a public sector body which is subject to any United Kingdom Competition Requirements

“United Kingdom Competent Authority” – means:

- (a) such persons officeholders and bodies (however constituted) that are specified under any United Kingdom Competition Requirement as having responsibility for monitoring compliance with and/or legally enforcing State Aid or United Kingdom Competition Requirements or otherwise authorised to recover any Unlawful State Aid; or
- (b) the courts of England and Wales.

“United Kingdom Competition Requirement” – means any Legislation which:

- (a) is in force and/or in effect and/or applies (in England) on or after the date the United Kingdom ceases to be a Member State of the European Union; and
- (b) which regulates any aid funding assets or advantage granted or directed by a public sector body to the extent that the same has the ability to threaten to or actually distort either competition or an economic market in the United Kingdom and/or in any part of the European Economic Area and/or in any other country or countries

“Unlawful State Aid” – means (as the case may be):

- (a) State Aid which has been granted in contravention of Article 108(3) Treaty of the Functioning of the European Union (TFEU), does not benefit from an exemption from notification and has not been approved by a decision of the European Commission under Article 107(2) or (3) TFEU; or
- (b) State Aid which has been granted after the United Kingdom ceases to be a Member State of the European Union to the extent that the same is granted contrary to or is an infringement of any United Kingdom Competition Requirement”

6. Public service obligation and State Aid

- 6.1 This LES and the State indemnity is drafted with the intention that it is lawful and complies with the requirements of the SGEI Decision.

- 6.2 The Provider is entrusted by the Commissioner to administer COVID-19 vaccines to the general public in accordance with this LES, relevant directions of the Secretary of State for Health and Social Care and any relevant Ministerial Decisions.
- 6.3 If the State indemnity gives rise to an SGEI Decision Overpayment or otherwise constitutes Unlawful State Aid then the Commissioner or the Secretary of State shall be entitled to recover from the Provider the amount of such SGEI Decision Overpayment and/or Unlawful State Aid together with such interest as it is required by Legislation to recover and the Provider must pay such amount(s) within ten (10) business days of the Commissioner or Secretary of State requesting repayment.
- 6.4 The Provider shall promptly give written notice to the Commissioner of any Public Sector Subsidy it receives from a third party in relation to any COVID-19 vaccine administration.
- 6.5 If the SGEI Decision ceases to apply in England then the Commissioner may, by providing written notice to the Provider, vary this LES to the extent necessary to remove those obligations which require compliance with it.
- 6.6 The Commissioner may, at its discretion, conduct an SGEI Review.
- 6.7 The Provider shall ensure that it (at its cost) co-operates with the Commissioner during an SGEI Review and it shall if requested promptly provide the Commissioner with SGEI Information and such other information, evidence and/or explanation as the Commissioner may reasonably require.

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Publication approval reference: