Classification: Official



# COVID-19 vaccination programme: Schedule (2A) 1 September 2024 to 31 March 2026



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# **COVID-19 vaccination programme: Schedule 2(A)**

#### 1 September 2024 to 31 March 2026

[This Schedule should be issued to Providers who participate in the COVID-19 Vaccination Site Signup Process Guidance and which are awarded a contract to administer COVID-19 vaccinations to JCVI Cohorts. It can be used in line with the Full Length and Shorter Form NHS Standard Contracts]

Service name		COVID-19 vaccination programme: 1 September 2024 to 31 March 2026					
Service specification number							
Population for Services	Patients (otherwise known as public cohorts)						
Service aims and desired outcomes	The aims of this service are to administer vaccinations as recommended by the JCVI and in accordance with the Green Book.  NHS Outcomes Framework Domains & Indicators						
		Domain 1	Preventing people from dying prematurely	~			
		Domain 2	Enhancing quality of life for people with long-term conditions	~			
		Domain 3	Helping people to recover from episodes of ill-health or following injury				
		Domain 4	Ensuring people have a positive experience of care	~			
		Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	~			
Service	[De	esignated Sit	e to be added by Commissioner]				
description and							
Designated							
Site from							
which it will be delivered							

#### 1. Introduction

- 1.1 The Provider has submitted a Response Document and has been awarded this arrangement to provide services in accordance with this Schedule 2A Service Specification of the Particulars of the NHS Standard Contract 2024/25. This Schedule 2A is subject to amendments from time to time as the COVID-19 vaccination programme develops and is subject to Ministerial Decision. This specification is not applicable to General Practitioners, Pharmacy Contractors or providers of vaccinations in Detained Estates settings.
- 1.2 This Schedule 2A will be included in an NHS Standard Contract (Shorter Form) where the Provider does not hold an NHS Standard Contract as at the Commencement Date and will be included by way of a variation to an NHS Standard Contract (for the relevant Financial Years) where the Provider does hold an NHS Standard Contract.
- 1.3 The Provider agrees to provide this service, including any variations and updates from the Commencement Date until the End Date of this Schedule 2A, unless terminated earlier in accordance with the terms of this Schedule or GC17.
- 1.4 No part of this Schedule by commission, omission or implication defines or redefines any relevant legislative provisions that may apply.
- 1.5 The vaccination programme is based on collaborative working and a systemwide approach to service delivery. There will be key interdependencies with the vaccine supply chain, Commissioner regional teams, ICSs and other providers commissioned to support the vaccination programme.
- 1.6 Related Patient (otherwise known as public cohorts) Schedules include Schedule 3 (Payment), and Schedule 6A (Reporting Requirements).

## 2. Commonly used terms

- 2.1 In this Schedule:
  - 2.1.1. "Commencement Date" means 1 September 2024 where the Provider submitted a Response Document on or before 23:59 on 27 June 2024 or the date notified by the Commissioner where the Provider submitted a Response Document after 23:59 on 27 June 2024;

- 2.1.2. "Commissioner" means NHS England;
- 2.1.3. "CQC" is the Care Quality Commission;
- 2.1.4. "DHSC" is the Department of Health and Social Care;
- 2.1.5. "Designated Site" means the premises nominated by the Provider and approved by the Commissioner in accordance with the Designation Process as premises to which the COVID-19 vaccine will be delivered and from which the COVID-19 vaccination will be administered to Patients unless otherwise in accordance with this Schedule 2A or agreed by the Commissioner;
- 2.1.6. "Designation Process" means the COVID-19 Assurance and Site Designation process set out in the Site Signup Process Guidance which is undertaken to ensure that the Designated Site meets the specified site criteria and which may be updated and amended as required from time to time and is an integral part of this Service and which shall confirm the Designated Site approved by the Commissioner;
- 2.1.7. "End Date" means 31 March 2026 unless: terminated earlier in accordance with this Schedule; or extended in accordance with paragraph 3.2;
- 2.1.8. "Expected Service Commencement Date" means the date from which the administration of COVID-19 vaccinations shall commence and which shall be following an announcement by the Commissioner. Where the date announced by the Commissioner is no less than 4 weeks following the Commencement Date, the administration of vaccinations shall commence from the date announced by the Commissioner. Where the date announced by the Commissioner is less than 4 weeks following the Commencement Date, the administration of vaccinations shall commence on a date to be agreed with the Commissioner. Where the Commencement Date is later than the date announced by the Commissioner the administration of vaccinations shall commence from the Commencement Date;
- 2.1.9. **"Flu Letter**" means the annual flu letter available at the following website as updated from time to time: https://www.gov.uk/government/collections/annual-flu-programme;

- 2.1.10. "GPhC" is the General Pharmaceutical Council;
- 2.1.11. "Green Book" is the Green Book: Immunisation against infectious disease published by UKHSA, which has the latest information on vaccines and vaccination procedures for all the vaccine preventable infectious diseases that may occur in the UK. For COVID-19 the appropriate chapter is available at the following website which is updated from time to time:
  https://www.gov.uk/government/publications/covid-19-the-green-book-chapter-14a;
- 2.1.12. "JCVI" is the Joint Committee on Vaccination and Immunisation;
- 2.1.13. "**JCVI Cohorts**" means the cohorts of Patients referenced by JCVI advice;
- 2.1.14. "MHRA" is the Medicines and Healthcare products Regulatory Agency;
- 2.1.15. "Ministerial Decision" is a decision issued by the Secretary of State for Health and Social Care;
- 2.1.16. "National Booking Service" or "NBS" is the national system used by Patients to book COVID-19 vaccination appointments;
- 2.1.17. "NICE" is the National Institute for Health and Care Excellence:
- 2.1.18. "Patient" means those patients (otherwise known as public cohorts) eligible to receive the relevant vaccination by their inclusion in a JCVI Cohort which has been announced and authorised by the Commissioner as eligible for vaccination by the Provider and as set out at paragraph 7;
- 2.1.19. "**Pause**" means a pause to the requirement for the administration of COVID-19 vaccinations as set out at paragraph 3.6;
- 2.1.20. "Point of Care System" means the National Immunisation and Vaccination System, which is a clinical system that has been authorised by NHS England to record COVID-19 vaccination events, unless exceptionally agreed in writing with the Commissioner or where the Commissioner requires a change of clinical system to be used by the Provider, which shall be notified to the Provider in writing and with reasonable notice. The vaccination

- event data will feed back to general practitioner systems and be used for national reporting;
- 2.1.21. "Private Patients" means any non-NHS Patients;
- 2.1.22. "Response Document" means the response to the COVID-19 Vaccination Site Signup Process Guidance whereby the Provider is awarded this arrangement to deliver the Services under this Schedule;
- 2.1.23. "Service User" in accordance with the General Conditions, is someone for whom the Commissioner has statutory responsibility and who receives Services under the NHS Standard Contract;
- 2.1.24. "Service(s)" means the provision of COVID-19 vaccinations to Patients only in the populations as set out at the start of this Schedule:
- 2.1.25. "Short Term/Temporary Site" means a clinically appropriate, short-term or temporary clinic run by the Provider to administer vaccinations (for example, a one-off clinic, a clinic running for a week, a clinic running twice a week for two weeks). This may be at or away from the Designated Site. The vaccine may only be stored overnight at CQC/GPhC registered premises in accordance with approved medicines management arrnagements and the Provider will use vaccine and any related consummables, and systems supplied to the Designated Site;
- 2.1.26. "Site Capacity" means at least 100 COVID-19 vaccinations per week which the Provider has offered to provide in its Response Document and has been set out in the Response Document [and has been agreed by the Commissioner to be administered during each week during of the Term];
- 2.1.27. "Surge" means an operational response for the management of a rapid short-term increase in capacity for COVID-19 vaccination as a consequence of a new variant or a specific instruction to vaccinate or revaccinate a defined population. It is a system change in line with JCVI Guidance to ensure the defined population in England is offered and has access to a COVID-19 vaccination;
- 2.1.28. "**Term**" means the period from the Expected Service Commencement Date to the End Date; and

#### 2.1.29. "UKHSA" is the UK Health Security Agency.

#### 3. Duration

- 3.1 This Schedule shall come into force on the Commencement Date and shall continue until 31 March 2026 unless it is extended in accordance with paragraph 3.2 or terminated in accordance with paragraph 3.5, 3.11 or GC17.
- 3.2 The Commissioner may, on no less than 21 days' notice to the Provider and no later than 21 days before the End Date, extend the Term by up to 12 months.
- 3.3 The administration of vaccinations shall commence with effect from the Expected Service Commencement Date.
- 3.4 Where the Provider is unable to commence the administration of vaccinations within 4 weeks of the Expected Service Commencement Date, the Provider must notify the Commissioner as soon as reasonably possible.
- 3.5 The Commissioner may agree with the Provider an extension not exceeding 8 weeks following the Expected Service Commencement Date to commence the administration of vaccinations. Failure to begin the administration of vaccinations within the agreed timeframe will result in termination of this Schedule on a date to be notified by the Commissioner to the Provider.
- 3.6 Where there is (in the reasonable view of the Commissioner) significantly reduced Patient demand for the administration of COVID-19 vaccinations, there is unacceptable wastage of the COVID-19 vaccine and/or the Designated Site does not represent acceptable value for money to the Commissioner, the Commissioner may require the Provider to suspend the Services (a "Pause").
- 3.7 Where the Provider does not agree to the Pause, they may provide evidence to the Commissioner detailing that there is not a significantly reduced Patient demand for the administration of COVID-19 vaccinations, there is not unacceptable wastage of the COVID-19 vaccine and/or the Designated Site represents acceptable value for money to the Commissioner and the Commissioner shall, acting reasonably, reconsider whether it remains appropriate to continue with the Pause.
- 3.8 During a Pause, the Provider shall not administer COVID-19 vaccinations in accordance with this Schedule and shall not be entitled to claim or receive any payment for the administration of COVID-19 vaccinations except in

respect of the Services which took place prior to the date on which the Pause occurred unless in the case of unavoidable and limited costs which have been exceptionally agreed with the Commissioner in advance of such costs being incurred.

- 3.9 While the Services are Paused the Commissioner and the Provider shall use all reasonable efforts to ensure that no further Patients are referred to the Provider for COVID-19 vaccination and should direct Patients to available services, as appropriate.
- 3.10 Where there is, in the reasonable view of the Commissioner a requirement to increase capacity at pace (Surge), the Provider shall agree with the Commissioner its role in the system wide response to the Surge, both in terms of increased volume and rapid timeframe for the administration of the vaccinations.
- 3.11 The Commissioner Notice Period for this Service is 42 days. The Commissioner Earliest Termination Date is 13 October 2024.

## 4. Vaccine supply and availability

- 4.1 The Provider will be provided with COVID-19 vaccines to deliver the Services. The vaccine must not be used to administer vaccinations to Private Patients. The Provider will have the ability to administer the Site Capacity (subject to the vaccine supply). The Provider and the Commissioner may agree to the vaccination or prioritisation of particular JCVI Cohorts.
- 4.2 The Provider should understand that the COVID-19 vaccine availability and supply may be challenging and may be constrained and is subject to change over time. The Commissioner may (acting reasonably) need to make allocation decisions regarding the COVID-19 vaccine during the Term of the Services. Allocation decisions could include prioritising providers or the use of a particular type of COVID-19 vaccine. The Commissioner will, where possible, arrange supply to meet local population need from providers that are best placed to meet that need and to enable the vaccine delivery as set out at paragraph 4.1. The Provider must provide support in relation to stock forecasting, use and ordering of COVID-19 vaccine as requested by the Commissioner.
- 4.3 The Provider must minimise COVID-19 vaccine wastage and support the high uptake of vaccinations.

## 5. Collaboration requirements

5.1 The Provider will work together with others in a collaborative manner and in accordance with the collaboration requirements of this Schedule to deliver all aspects of this specification.

#### 5.2 The Provider will:

- 5.2.1 comply with any reasonable request for information from the Commissioner relating to the provision of the Services pursuant to this Schedule:
- 5.2.2 have regard to all relevant guidance published by the Commissioner or referenced within this Schedule;
- 5.2.3 comply with all clinical protocols giving explicit consideration to contra-indications and any guidance around concurrent administration of vaccinations (e.g., pneumococcal, pertussis or influenza vaccinations);
- 5.2.4 take reasonable steps to provide information (supplementary to national communications) to Patients about the Services pursuant to this Schedule, including information on how to access the Services and any changes to them; and
- 5.2.5 ensure that it has in place suitable arrangements to enable the lawful sharing of data to support the delivery of the Services, business administration and analysis activities.

## 6. Site designation and premises requirements

- 6.1 The Provider will have nominated and have access to the Designated Site as set out in its Response Document.
- 6.2 The Commissioner will approve the Designated Site in accordance with the Response Document and Designation Process.
- Any amendments, additions or removal of a Designated Site shall only be permitted with the agreement of the Commissioner.
- 6.4 From the Commencement Date to the End Date, the Commissioner shall be entitled to access and inspect the Designated Site in accordance with GC15.

- 6.5 Vaccinations administered in accordance with this Schedule must be administered at the Designated Site unless:
  - 6.5.1 required by the Commissioner in accordance with paragraph 6.8; or
  - 6.5.2 the Provider notifies the Commissioner (in advance) that it intends to deliver a Short Term/Temporary Site for the administration of vaccinations and to improve vaccination uptake on given date(s) and/or time(s) to permit vaccination of specific Patient groups).
- 6.6 The majority of vaccinations must take place at the Designated Site.
- Vaccinations can be offered in any area where suitable facilities are available, infection control standards can be maintained, and patient confidentiality and dignity is able to be respected. Vaccinations must take place in a consultation room whenever the patient expresses this preference.
- 6.8 Where a Patient is unable to access the Designated Site and the Commissioner (acting reasonably) requires the Provider to make arrangements to vaccinate patients in other suitable locations, such as in the Patient's home, a long-stay care home, or a long-stay residential facility, the Provider must make these arrangements within 8 weeks of the Commissioner requirement being communicated to the Provider, or as soon as reasonably possible, as agreed in advance with the Commissioner. The delivery of vaccinations in accordance with this paragraph 6.8 is not Short Term/Temporary Site activity, which must be notified to the Commissioner in accordance with paragraph 6.5.2.
- 6.9 Where vaccinations are administered at locations other than the Designated Site in accordance with paragraph 6.5 and/or 6.8, the Provider must continue to ensure that appropriate measures are taken to ensure the integrity of the cold chain as well as meeting all other relevant standards.
- 6.10 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 Provider must ensure that the relevant vaccinator has a Disclosure and Barring Service (DBS) certificate.
- 6.11 The Provider must ensure appropriate processes are in place to dispose of any clinical waste, vaccine packaging and personal protective equipment (PPE) used during the vaccination process.
- 6.12 The Provider is required to comply with reasonable requests from the Commissioner or waste disposal company to facilitate the safe and secure

- removal and safe disposal of clinical waste and PPE related to the provision of this Service.
- 6.13 The Provider must inform the Commissioner immediately if, for any reason, a Designated Site ceases to meet the criteria set out in this Schedule.

## 7. Patient eligibility

- 7.1 Nothing in this Schedule shall interfere with the obligations placed on the Provider by SC21.4 (Full Length NHS Standard Contract) or paragraph 8.6 (Shorter Form NHS Standard Contract) as applicable, or permit the Provider to provide any other vaccination services.
- 7.2 The Provider shall only vaccinate Patients eligible to receive the vaccination by their inclusion in a JCVI Cohort which has been announced and authorised by the Commissioner as eligible for vaccination by the Provider.
- 7.3 The Commissioner will announce the authorisation of JCVI Cohorts for vaccination by the Provider.
- 7.4 The Provider must administer the vaccinations to Patients in the priority order announced and authorised by the Commissioner.
- 7.5 The Provider acknowledges that the authorisation of and priority order of JCVI Cohorts will change throughout the Term and must ensure that it complies with the announcements, authorisations and priority orders in place at the date of the administration of vaccinations, throughout the Term.

## 8. Service description

#### 8.1 The Provider must:

- 8.1.1 ensure that vaccinations are provided in line with the Green Book, including relevant details on the treatment of anaphylaxis and secure storage and disposal of clinical waste. The Provider must ensure that they have a process in place to check any updates to the Green Book:
- 8.1.2 only administer vaccinations during the Term of this Schedule;
- 8.1.3 comply with any relevant guidance and Standard Operating Procedures relating to delivery of local vaccination services and continue to meet the designation criteria as set out in the Designation Process:

- 8.1.4 identify people eligible for COVID-19 vaccination who present at the Provider and encourage them to be vaccinated; and
- 8.1.5 ensure that, where the vaccination is part of a multi-dose regimen, the Patient receives the correct dosage of the vaccine, as is clinically appropriate, and that the Patient is advised that failure to receive all doses may render vaccination less effective. The Provider should encourage the Patient to make or attend a follow up appointment to receive any subsequent dose(s).
- 8.2 The Provider must follow all current guidance published by the JCVI, the Commissioner, DHSC, MHRA, NICE 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;
  - 8.2.3 the intervals between doses where multiple doses are required;
  - 8.2.4 the number of doses of each vaccine required to achieve the desired immune response; and
  - 8.2.5 any other relevant guidance relating to the administration of the different types of vaccine and the different JCVI Cohorts from time to time.
- 8.3 In the event of a conflict between guidance issued by the JCVI, the Commissioner, DHSC, MHRA, NICE and/or UKHSA, the Commissioner shall confirm which guidance shall be adopted.
- 8.4 Each Patient being administered a vaccination must be given written information about the vaccine as specified by UKHSA.<sup>1</sup> A copy of the manufacturer's patient information leaflet must also be provided to the Patient (or the Patient may be directed to a web-based version of that leaflet where the Patient agrees). Where required, Patients should also be informed of any current policy as recommended by the JCVI in relation to the timing of the administration of any necessary subsequent dose where this is not reflected in the manufacturer's patient information leaflet.

<sup>&</sup>lt;sup>1</sup> https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination

- 8.5 The Provider must ensure that they have in place suitable arrangements to prevent the disruption of other services that it provides to NHS commissioners.
- 8.6 Where this Schedule is included in a NHS Standard Contract (Shorter Form):
  - 8.6.1 the Provider must use all reasonable endeavours to ensure that all eligible frontline Staff in contact with Service Users are vaccinated, in accordance with JCVI and Green Book Guidance, against influenza and COVID-19; and
  - 8.6.2 the Provider must use all reasonable endeavours to ensure that, where Staff have any contact with a Service User who is either immunosuppressed and/or pregnant (other than while that Service User is an inpatient), they provide that Service User with brief advice on COVID-19 vaccination, in accordance with JCVI and Green Book Guidance, including on available routes for accessing a vaccination service:

in line with SC21.4 and SC21.5 of the Full Length NHS Standard Contract.

8.7 The Provider should advise the Patient attending at the Designated Site for vaccination about other services that are available from NHS providers locally. This could include, but is not limited to, the provision of health promotion materials, details of services and providers of those services in the local area, signposting to an online list of services in the local area and general advice and guidance. This should include signposting eligible Patients to other vaccinations and where these are available from.

## 9. Patient access and service availability

- 9.1 The Provider must ensure that they comply with SC13. Patients do not require an NHS number and should not be denied vaccination on this basis.
- 9.2 The Provider must offer COVID-19 vaccinations through the NBS. They must comply with the requirements of the NBS, including in ensuring that accurate information is published and in uploading appointment / clinic times in a timely way to allow Patient bookings to take place.
- 9.3 Patients who have booked appointments with the NBS may ordinarily have eligibility confirmed prior to booking. The Provider must confirm each Patient's eligibility prior to administration of the vaccination.

- 9.4 The Provider must ensure that any Patient whose appointments are not made through the NBS are eligible for a vaccination as set out in this Schedule and that arrangements are made for administration of any subsequent dose(s) of a multi-dose regimen where appropriate.
- 9.5 The Provider is strongly encouraged to offer vaccinations through advertised walk-in clinics or alternative arrangements to improve uptake or engagement with communities as agreed with the Commissioner. Processes must be put into place to support Patients with communication needs and/or encourage vaccination of Patients who experience other difficulties in accessing healthcare.
- 9.6 The Provider may be required to operate regular clinics in the evenings, at weekends and on bank holidays to meet the needs of the local population as agreed by the Commissioner. Actual delivery hours shall be agreed with the Commissioner having regard to the Site Capacity, JCVI guidance on dosing intervals, the size of the local population eligible for vaccination and available vaccine supply.
- 9.7 In the event that the Provider needs to temporarily suspend the administration of vaccinations in accordance with this Schedule, this shall be agreed with the Commissioner and relevant changes must be made as soon as practicably possible to the NBS.
- 9.8 Where there are necessary changes to planned appointments/clinics, the Provider shall work with the Commissioner and shall communicate any such changes to relevant Patients.

#### 10. Assessment and consent

- 10.1 The Provider must, in line with SC9 (or where this Schedule is included in a NHS Standard Contract (Shorter Form) the Provider must publish, maintain and operate a Service User consent policy which complies with Good Practice and the Law):
  - 10.1.1 ensure that a registered healthcare professional, trained in vaccination administration and familiar with the characteristics of the vaccine being administered, assesses the Patient as eligible and suitable clinically in accordance with law and guidance prior to administering the vaccination. This assessment should include providing reasonable information that the Patient may require to make a final decision on whether to proceed with the vaccination;

- 10.1.2 ensure that informed Patient consent is obtained by a registered healthcare professional and the Patient's consent to the vaccination (or the name of the person who gave consent to the vaccination and that person's relationship to the Patient) is recorded in the Point of Care System and in accordance with law and guidance. Should the Patient decline the vaccination at any stage, this must also be recorded in the Point of Care System;
- 10.1.3 ensure that the Patient is informed about the handling of their information in relation to the provision of this arrangement (which will include the sharing that will take place for the appropriate recording of the vaccination in their general practice record) including advising the Patient that information may be anonymised and used by the Commissioner (or their agents) for the purposes of service delivery, evaluation and research; and
- 10.1.4 comply with any relevant clinical checklists (including checklists relevant to the vaccination of those under 18 years of age).

## 11. Training

- 11.1 The Provider must ensure, in line with GC5.5, (or where this Schedule is included in a NHS Standard Contract (Shorter Form) GC5.5 shall be incorporated into this paragraph 11.1) that every member of Staff has received proper and sufficient training and instruction in relation to the administration of vaccination to the Patient.
- 11.2 All persons involved in the provision of the Services (whether delivering vaccinations directly or supervising others providing vaccinations) must adhere to all relevant professional standards, regardless of the setting.
- 11.3 Vaccinations must be administered by an appropriately trained member of staff authorised under an appropriate legal mechanism (for example the UKHSA Patient Group Directions or National Protocols<sup>2</sup>).
- 11.4 All persons involved in the preparation of the vaccine must be appropriately trained 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.

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<sup>&</sup>lt;sup>2</sup> https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanisms/

- 11.5 The Provider must ensure that all persons involved in the administration of vaccinations have received appropriate and adequate training and are competent in the administration of those vaccinations. All persons involved in the administration of the vaccination must:
  - 11.5.1 have completed the additional online COVID-19 specific training modules available on the e-learning for healthcare website<sup>3</sup>;
  - 11.5.2 have the necessary experience, skills and training<sup>4</sup> including training with regard to the recognition and initial treatment of anaphylaxis;
  - 11.5.3 administer the vaccination in accordance with the most up to date version of the clinical guidance available including the relevant chapter of the Green Book; and
  - 11.5.4 be authorised by and understand the appropriate legal mechanism for administration of the vaccination (for example, the UKHSA Patient Group Directions or National Protocols)<sup>5</sup>.
- 11.6 The Provider must ensure be assured to administer all COVID-19 vaccine types as required by the Commissioner.
- 11.7 The Provider must ensure that they are familiar with all guidance relating to the administration, handling and storage of the different types of vaccine and that they take steps to reduce risks associated with the handling of different vaccine types.
- 11.8 The Provider must oversee and keep a record to confirm that all staff have undertaken the relevant training prior to participating in the administration of vaccinations. This includes any additional training associated with new vaccines that become available during the period of this Schedule.

## 12. Vaccine handling and storage

12.1 The Provider must ensure that that all vaccines are received, stored, prepared and subsequently transported (where appropriate) in accordance with the relevant manufacturer's, the UKHSA's<sup>6</sup> and the Commissioner's instructions and all associated guidance set out in the 'Storage distribution

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<sup>&</sup>lt;sup>3</sup> https://portal.e-lfh.org.uk/Component/Details/675208

<sup>&</sup>lt;sup>4</sup> https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators

<sup>&</sup>lt;sup>5</sup> https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/legal-mechanism

<sup>&</sup>lt;sup>6</sup> UKHSA (previously PHE's) ordering, storing and handling protocol <a href="https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines">https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines</a>

and disposal of vaccines chapter of the Green Book' and all associated Standard Operating Procedures. Receipt, storage, transport and preparation of vaccines used pursuant to this Schedule must also be undertaken with appropriate cold chain management, clinical oversight and in accordance with governance arrangements in place for this Schedule.

- 12.2 The Provider must ensure that any refrigerator used to store vaccines has sufficient space to store different vaccine types, with separation to reduce the risk of selection errors, and sufficient airflow to maintain effective cooling. All refrigerators in which vaccines are stored must have a thermometer that records maximum and minimum temperatures appropriate to the vaccine being administered. Readings must be recorded from that thermometer on all working days and appropriate action taken when readings are outside the recommended temperature.
- 12.3 Appropriate procedures must be in place to ensure stock rotation, monitoring of expiry dates and appropriate use of multi-dose vials to ensure that wastage is minimised and stock holdings of vaccine remain low to support the maximisation of vaccinations to the population.

#### 12.4 COVID-19 vaccines:

- 12.4.1 are allocated to the Provider and the Provider must not share the vaccine with other providers providing a similar vaccination service, or move the vaccine (except as expressly permitted by this Schedule 2A), without the express prior consent of the Commissioner; and
- 12.4.2 will be supplied to the Designated Site. The Provider will be responsible for the supply of consumables as may be required (for example PPE and items related to Infection Prevention and Control). The Provider must be available to accept vaccine deliveries at the Designated Site according to the delivery schedule provided by the Commissioner.
- The Provider will support any national, regional and system processes in relation to COVID-19 vaccine stock forecasting and ordering arrangements, which will include complying with the processes and requirements set out in any relevant Standard Operating Procedures. This will include providing weekly updates on actual COVID-19 vaccine stock and may include, for example, providing daily or weekly updates on actual stock use, COVID-19 vaccines delivered (including the brand of COVID-19 vaccine used), COVID-19 vaccine wastage and forecasted requirements. The Provider will need to

submit information using a specified national system. Stock availability may be linked to the forecasted number of eligible Patients locally.

## 13. Monitoring, reporting and record keeping

- 13.1 The Provider must have signed up to receive the COVID-19 Vaccination Bulletin (or any replacement to the COVID-19 Vaccination Bulletin) by the Commencement Date and ensure they receive the COVID-19 Vaccination Bulletin published by the Commissioner so key information in relation to the delivery of this Schedule can be communicated in a timely manner.
- 13.2 The Provider must monitor and report all activity information in accordance with the monitoring and reporting standards as published by the Commissioner and in accordance wiith Schedule 6A. This includes guidance published by the Commissioner on the recording of COVID-19 vaccination appointments to ensure consistent national data captures.
- 13.3 The Provider must ensure that any staff recording the vaccination have received relevant training to be able to update records appropriately and accurately. There must be robust user and access management processes to ensure high levels of security, including frequent updates to system access levels to add users who join the site team or remove accounts where staff leave employment or do not have shifts scheduled at the site.
- 13.4 The Provider must adhere to defined standards of record keeping ensuring that the vaccination event is recorded the same day that it is administered within an approved Point of Care System<sup>7</sup>.
- 13.5 Where the Point of Care System is unavailable due to exceptional circumstances beyond the control of the Provider, then the record of vaccination events must be added to the Point of Care System as soon as possible after the Point of Care System becomes available again. The Commissioner must be notified if this will result in records of vaccinations being added to the Point of Care System on a different day than the vaccinations were administered. Where the record of the vaccination event is not created within 15 days of the vaccination being administered, the Provider shall not be eligible for the payments as set out at Schedule 3. Where the payments are claimed and/or automatically submitted payments shall be recoverable by the Commissioner.

<sup>&</sup>lt;sup>7</sup> https://digital.nhs.uk/services/vaccinations-point-of-care/looking-to-onboard-to-a-point-of-care

- 13.6 Where a record of the vaccination needs to be amended or has not been created on the Point of Care system, the Provider is responsible for undertaking the amendment or creation as soon as reasonably possible following notification that the record contains an error.
- 13.7 The Commissioner will provide access to an online Point of Care System for making records of vaccinations.
- 13.8 The Provider:
  - 13.8.1 must only enter new vaccinations into a single Point of Care System in any calendar month except:
    - a) during the transition to a new Point of Care System where the use of two systems will be permitted for a period determined by the Commissioner; or
    - b) subject to paragraph 13.6, where it is necessary to include amendments to vaccination events previously recorded.
  - 13.8.2 is responsible for ensuring that the quality and connectivity of internet broadband at the Designated Site is sufficient to support access to the Point of Care System during the hours of operation or as agreed with the Commissioner.
- 13.9 The Provider must comply with any reasonable request for information from the Commissioner relating to the provision of the Services under this arrangement.
- 13.10 The Provider is responsible for recording adverse events and providing the Patient with information on the process to follow if they experience an adverse event in the future after leaving the vaccination site, including signposting the Yellow Card service. The Provider is expected to follow the UKHSA: Vaccine incident guidance, responding to errors in vaccine storage, handling and administration.
- 13.11 The Provider must maintain appropriate records to ensure effective ongoing delivery and governance. Records must be managed in line with 'Records Management Code of Practice for Health and Social Care.8

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<sup>&</sup>lt;sup>8</sup> https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-and-social-care

# 14. Sub-contracting arrangements

14.1 Any sub-contracting must be in line with GC.12.