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Enhanced Service Specification

COVID-19 vaccination programme: [1] September
2022 to 31 March 2023 (phase 5)

30 June 2022, Version 1.0

Enhanced Service (ES) Specification

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Equalities and health inequalities statement

"Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it;
- given regard to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in ensuring that services are provided in an integrated way where this might reduce health inequalities."

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1 Introduction

- 1.1 This ES¹ is subject to amendments from time to time as the COVID-19 vaccination programme develops.
- 1.2 This ES has been developed from the COVID-19 vaccination programme (phase 4 enhanced service specification). It is a national specification that cannot be varied locally.
- 1.3 This ES is offered by the Commissioner (NHSE) to all General Medical Services, Personal Medical Services and Alternative Provider Medical Services contract holders.
- 1.4 An ES is designed to cover enhanced aspects of clinical care, all of which are beyond the scope of essential and additional services. No part of this ES specification by commission, omission or implication defines or redefines essential or additional services.
- 1.5 All GP practices are offered the opportunity to sign up to this ES, provided they meet the requirements of this specification. By signing up to deliver this ES, a GP practice agrees to a variation of its primary medical services contract to incorporate the provisions of this ES. The provisions of this ES are therefore deemed a part of the GP practice's primary medical services contract.
- 1.6 A GP practice need not be a member of an established Primary Care Network or an established PCN grouping to participate in this ES. GP practices are expected to collaborate with neighbouring practices to deliver this ES and established Primary Care Networks in a 'PCN grouping' to deliver all aspects of this ES. GP practices may wish to utilise PCN groupings which were established to deliver earlier phases of the ES or may wish to form an alternative PCN grouping to deliver this ES. All collaborating GP practices, whether they are members of an established Primary Care Network or not, will be expected to sign up to a COVID-19 ES Vaccination Collaboration Agreement as described in this ES. Where a PCN grouping remains unchanged from the delivery of the services under earlier phases of the ES, GP practices may update their COVID-

¹ Section 7A functions are arrangements under which the Secretary of State delegates to NHS England responsibility for certain elements of the Secretary of State's public health functions, which add to the functions exercised by NHS England under the National Health Service Act 2006 ("the 2006 Act"). They are made under section 7A of the 2006 Act. They are described as 'reserved functions' which are not covered by the 'enhanced services delegated to CCG' category in the delegation agreement. NHS England remains responsible and accountable for the discharge of all the Section 7A functions. As this vaccination is defined as a Section 7A function, this agreement cannot be changed or varied locally.

19 ES Vaccination Collaboration Agreement to include the delivery of services under this ES.

- 1.7 GP practices can advise the Patient attending for vaccination about other 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 to other vaccinations where, if eligible, the Patient indicates that they have not made arrangements for this vaccination and the Patient does not elect or it is not possible to have a co-administered vaccine (where the GP practitioner is able to offer this).
- 1.8 Where this ES sets out a requirement or obligation of a PCN grouping, each GP practice is responsible for ensuring the requirement or obligation is carried out on behalf of that PCN grouping.

2 Commonly Used Terms

- 2.1 This specification is referred to as this “**ES**”.
- 2.2 In this ES:
- 2.2.1 the “**Commissioner (NHSE)**” refers to the National Health Service Commissioning Board, also known as NHS England
- 2.2.2 “**COVID-19 ES Vaccination Collaboration Agreement**” refers to the agreement entered into by GP practices, including those that are members of an established Primary Care Network, and which incorporates the provisions that are required to be included in a COVID-19 ES Vaccination Collaboration Agreement in accordance with paragraph 6.5;
- 2.2.3 a “**Designated Site**” refers to premises nominated by the PCN grouping and approved by the Commissioner (NHSE) in accordance with the Designation Process as the premises from which the vaccination will be administered to Patients. Only one PCN grouping shall be permitted to operate from each Designated Site;
- 2.2.4 the “**Designation Process**” refers to the General Practice Site Designation Process (which includes the site designation criteria) which is undertaken to ensure that any site delivering vaccinations under this ES 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 ES. A copy of the Designation Process (as may be amended from time to time) is published on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/primary-care-guidance/>;

- 2.2.5 a “**GP practice**” refers to a provider of essential primary medical services to a registered list of patients under a General Medical Services contract, Personal Medical Services agreement or Alternative Provider Medical Services contract who has agreed with the Commissioner (NHSE) to deliver this ES;
- 2.2.6 “**JCVI**” means the Joint Committee on Vaccination and Immunisation;
- 2.2.7 “**MHRA**” means the Medicines and Healthcare products Regulatory Agency;
- 2.2.8 “**Ministerial Decision**” means a decision issued by the Secretary of State for Health and Social Care;
- 2.2.9 “**National Booking Service**” means the national system used by Patients to book coronavirus (COVID-19) vaccination appointments;
- 2.2.10 “**Patient**” means those patients eligible to receive the vaccination in general practice as set out at paragraphs 9.1 to 9.3;
- 2.2.11 “**PCN grouping**” refers to the group of GP practices which collaborate to deliver the services under this ES, which may include established Primary Care Networks, and additional neighbouring GP practices and/or other groups of GP practices working together;
- 2.2.12 “**Point of Care System**” refers to a clinical system that has been assured by NHS Digital to record COVID-19 vaccination events;
- 2.2.13 “**Surge**” means an operational response for the management of a rapid short-term increase in capacity as a consequence of a new variant or a specific instruction to vaccinate or revaccinate a defined population. It is a system change in line with JCVI Guidance to ensure the defined population in England is offered and has access to a Covid 19 vaccination; and
- 2.2.14 “**UKHSA**” means the UK Health Security Agency.

2.3 In this ES words importing the singular include the plural and vice versa.

- 2.4 References to anybody, organisation or office include reference to its applicable successor from time to time.

3 Duration

- 3.1 This ES is for the Commissioner (NHSE) to commission the provision of COVID-19 vaccinations to Patients. This ES begins on 1 September 2022 and shall continue for an initial period until 31 March 2023 unless it is terminated in accordance with paragraph 3.6. The Commissioner (NHSE) shall be entitled to extend the term on one or more occasions by notifying the GP practice provided that the duration of this ES shall be no longer than one year.
- 3.2 From 1 January 2023, where there is (in the reasonable view of the Commissioner (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 GP Practice together with the other GP Practices in the PCN Grouping to suspend the services (a “Pause”).
- 3.3 Where the GP practice together with the other GP practices in the PCN Grouping do 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.
- 3.4 During a Pause, the GP practice shall not administer COVID-19 vaccinations and shall not be entitled to claim or receive any payment 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 (NHSE) in advance of such costs being incurred.
- 3.5 While the services are Paused the Commissioner (NHSE) and the GP practice shall use all reasonable efforts to ensure that no further Patients are referred to the GP Practices within the PCN Grouping for vaccination and should direct Patients to available services, as appropriate.
- 3.6 Where there is, in the reasonable view of the Commissioner (NHSE) a requirement to increase capacity at pace to respond to a Surge, GP practices

shall agree with the Commissioner (NHSE) their role in the system wide response to the Surge, both in terms of increased volume and rapid timeframe.

- 3.7 This ES may be terminated on any of the following events:
- 3.7.1 automatically when the COVID-19 vaccination programme comes to an end;
 - 3.7.2 by the Commissioner (NHSE) providing not less than 42 days' notice to the GP practice; or
 - 3.7.3 by the GP practice providing not less than 42 days' notice to the Commissioner (NHSE), unless otherwise agreed with the Commissioner (NHSE).
- 3.8 GP practices will be provided with vaccines to deliver this ES. The GP practice will agree in writing with the Commissioner (NHSE) the minimum number of vaccinations per week which the GP practice as part of the PCN grouping shall be prepared to administer (subject to vaccine supply) prior to the commencement of vaccinations under this ES. This may include vaccination of specified cohorts of Patients.
- 3.9 The GP practice, together with the other GP practices in the PCN grouping shall be considered joint and several owners of the vaccine.
- 3.10 GP practices should understand that the vaccine availability and supply is challenging and 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 ES. Allocation decisions could include prioritising GP practices' PCN groupings or the use of a particular type of vaccine. The Commissioner (NHSE) will, where possible, arrange supply to meet local population need from providers that are best placed to meet that need and to enable the minimum vaccine delivery as set out at paragraph 3.8. GP practices' support in relation to stock forecasting, use and ordering is important to this ES.
- 3.11 The GP practice and the Commissioner (NHSE) agree that vaccinations under this ES shall not take place where earlier phases of the ES remain in force between the GP practice and the Commissioner (NHSE). The GP practice and the Commissioner (NHSE) agree that the earlier phase of the ES shall automatically terminate on the coming into force of this ES.
- 3.12 This ES will be updated from time to time as the vaccination programme develops and is subject to Ministerial Decision.

3.13 Details of this ES and the wider COVID-19 vaccination programme can be found at <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/>.

3.14 On termination of this ES, GP practices shall work with the Commissioner (NHSE) and any providers commissioned by the Commissioner (NHSE) for the delivery of any subsequent doses of vaccination to Patients.

4 Sign up process

4.1 GP Practices with sufficient workforce capacity so as not to impact the delivery of essential services and appropriately trained and experienced staff must indicate their willingness to participate in this ES before 17.00 on 14 July 2022 unless otherwise agreed by the Commissioner (NHSE).

4.2 Where the Commissioner (NHSE) is assured that the GP practices can comply and have the capacity to deliver this ES alongside their existing contractual requirements (and in compliance with any published guidance) the Commissioner (NHSE) will approve sign up to participate in this ES. The Commissioner (NHSE) must record their agreement to participate in this ES in writing. Local CCGs may be asked to support the Commissioner (NHSE) in the administrative elements of this.

5 Collaboration Requirements: General

5.1 Each GP practice will work together with others in a collaborative manner and in accordance with the collaboration requirements of this ES to deliver all aspects of this specification.

5.2 Each GP practice participating in this ES will:

5.2.1 co-operate with others in so far as is reasonable, including any other person responsible for the provision of services pursuant to this ES and/or the wider COVID-19 vaccination programme, or for the provision of any subsequent doses of the vaccine after the termination of this ES, in a timely and effective way and give to each GP practice in its PCN grouping and outside of its PCN grouping (where appropriate) such assistance as may reasonably be required to deliver the services under this ES;

5.2.2 openly, honestly and efficiently share information with other relevant parties including the GP practices in its PCN grouping and outside of its

PCN grouping (where appropriate) that is relevant to the services, aims and objectives of this ES;

- 5.2.3 comply with any reasonable request for information from the Commissioner (NHSE) relating to the provision of the services pursuant to this ES;
- 5.2.4 have regard to all relevant guidance published by the Commissioner (NHSE) or referenced within this ES;
- 5.2.5 comply with all clinical protocols giving explicit consideration to contra-indications and any guidance around concurrent administration of vaccinations (e.g influenza vaccinations);
- 5.2.6 take reasonable steps to provide information (supplementary to national communications) to Patients about the services pursuant to this ES, including information on how to access the services and any changes to them; and
- 5.2.7 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 Collaboration Requirements: PCN groupings

- 6.1 GP practices are expected to work in their PCN grouping to co-ordinate and deliver the vaccinations at scale and in line with the requirements set out in this ES.
- 6.2 The Patients who attend for COVID-19 vaccinations will attend what is deemed to be a temporary single medical practice for the purpose of regulation 3(8)(b) and 3A(1) of the Human Medicines Regulations 2012 (as amended).
- 6.3 GP practices are expected to participate in relevant PCN grouping meetings relating to the COVID-19 vaccination programme, in so far as is reasonable.
- 6.4 All GP practices participating in this ES must ensure that they collaborate with other GP practices in the PCN grouping in accordance with the Designation Process and agree (prior to participating in the ES) the site to be nominated as the Designated Site for delivering vaccinations under this ES.
- 6.5 All GP practices must have in place a COVID-19 ES Vaccination Collaboration Agreement signed by all collaborating GP practices in its PCN grouping by no

later than 31 August 2022 or such other date as may be agreed by the Commissioner (NHSE) that sets out the clinical delivery model (i.e. how clinics are delivered and responsibility is shared between the GP practices within the PCN grouping), deployed by the PCN grouping and as a minimum contains additional provisions in relation to the following:

- 6.5.1 appropriate arrangements for Patient record sharing in line with data protection legislation, including to enable GP practices to access information on the name and the manufacturer of any COVID-19 vaccinations previously received by the Patient;
- 6.5.2 appropriate arrangements for reporting of activity data, vaccine stock (to include stock use and stock forecasting which must include the brand of vaccine delivered and required by the PCN grouping), available capacity and submission of required data to the Commissioner (NHSE). Where appropriate access to mandatory national systems is required, these will be made available free of charge;
- 6.5.3 appropriate arrangements for communicating with Patients, including but not limited to call/re-call;
- 6.5.4 arrangements for any sharing and deployment of staff as agreed by the PCN grouping in relation to the efficient delivery of the services pursuant to this ES;
- 6.5.5 financial arrangements between the collaborating GP practices and, if relevant, financial arrangements relating to other healthcare providers (such as community pharmacies) outside of its PCN grouping involved in local delivery of this ES;
- 6.5.6 arrangements in relation to use of the Designated Site and any other relevant premises (as required);
- 6.5.7 sub-contracting arrangements (as required);
- 6.5.8 a lead contact email address for the PCN grouping which shall be supplied to the Commissioner (NHSE) for use in disseminating information urgently;
- 6.5.9 appropriate indemnity arrangements. The Clinical Negligence Scheme for General Practice (CNSGP) provides clinical negligence indemnity cover for all staff engaged by a GP practice under the CNSGP Regulations. It covers NHS activities delivered by a Part 4 contractor

under a Primary Medical Services contract (including under Schedule 2L of an NHS standard contract), Primary Medical Services delivered by a sub-contractor, and the provision of 'Ancillary Health Services' by or for a Part 4 contractor or Primary Medical Services sub-contractor. Cover under CNSGP is not restricted to a GP practice's registered patients so would apply to the provision of any NHS COVID-19 vaccinations by a GP practice to a person, including where they are not on the registered list of that GP practice;

6.5.10 appropriate arrangements to ensure that GP practices can identify, if appropriate, which Patients receive vaccinations under this ES and under earlier phases of the ES; and

6.5.11 where the collaborating GP practices consider that it is operationally expedient to do so, the COVID-19 ES Vaccination Collaboration Agreement shall set out the arrangements as between the collaborating GP practices for the co-administration of the COVID-19 vaccine and the seasonal influenza vaccine. Co-administration shall at all times be in line with the provisions set out in the [Green Book](#).

6.6 The Commissioner (NHSE) has published a template COVID-19 ES Vaccination Collaboration Agreement on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/primary-care-guidance/>, which the PCN grouping may wish to use and adapt for the purpose of delivering this ES.

6.7 PCN groupings will be expected to collaborate with any national, regional and system processes in relation to 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 PCN groupings providing weekly updates on actual stock and may include, for example, providing daily or weekly updates on actual stock use, vaccines delivered (including the brand of vaccine used), vaccine wastage and forecasted requirements. PCN groupings will need to submit information using the national Foundry system. Stock availability may be linked to the forecasted number of eligible patients locally.

6.8 PCN groupings will need to plan service delivery arrangements in line with stock forecasting and ordering arrangements including:

6.8.1 planning clinics according to expected vaccine supply;

6.8.2 coordinating required trained staff;

- 6.8.3 ordering required vaccine supply within required timeframes from the National Programme and ordering required consumables supply, where necessary from their chosen supply channel within required timeframes to ensure service continuity;
 - 6.8.4 receiving and safely storing supply;
 - 6.8.5 amending clinic schedules if there is a disruption to supply and undertaking timely communication of any changes to Patients; and
 - 6.8.6 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 GP practice and minimise the number of attendances required for Patients to receive these vaccinations.
- 6.9 The COVID-19 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.”
- 6.10 Where a PCN grouping signs up to use the National Booking Service it must comply with the conditions of sign up. From the point that the PCN grouping is onboarded to the National Booking Service, this must be the main booking system that the PCN grouping uses for vaccination appointments.

7 Site Designation

- 7.1 All GP practices participating in this ES must have nominated and have access to a Designated Site from which vaccinations must be administered unless specific guidance is provided by the Commissioner (NHSE) setting out the circumstances in which a vaccination can occur at a different location and/or there is a specific reason not to including:
- 7.1.1 where the medical condition of a Patient is such that, in the reasonable opinion of the GP practice, attendance on the Patient is required and it would be inappropriate for the Patient to attend at the Designated Site, the GP practice must provide the vaccination to the Patient at another location; and

- 7.1.2 that GP practices must make arrangements to vaccinate Patients resident in care homes at their care home of residence.
- 7.2 GP practices must include their nominated Designated Site in their sign-up confirmation in accordance with paragraph 4.1.
- 7.3 The Commissioner (NHSE) will approve Designated Sites in accordance with the Designation Process. Where a PCN grouping remains unchanged from earlier phases of the ES and the Designated Site for the delivery of this ES is the same as the Designated Site for the earlier phases of the ES, GP practices should expect that Designated Sites located on NHS estate will be approved by the Commissioner (NHSE) where that Designated Site demonstrates good access for Patients and value for money. Where Designated Sites are not on NHS estates, the GP Practice may be required to demonstrate equivalent value for money or exceptional circumstances (for example, high utilisation or appropriate access in areas of lower uptake) which require the use of the nominated Designated Site.
- 7.4 The Commissioner (NHSE) shall determine whether any proposed premises meets (and is likely to continue to meet) the requirements of the Designation Process while having regard to issues of Patient access, the geographical distribution of sites, the total number of Designated Sites that can be accommodated within vaccine supply arrangements and value for money. The Commissioner (NHSE) shall have regard to the PCN groupings' preferences. The Commissioner (NHSE) shall have the right to choose between multiple premises put forward by a PCN grouping.
- 7.5 Vaccines may be administered at locations other than the Designated Site with the prior consent of the Commissioner (NHSE). Where such consent is provided, the PCN grouping 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. Guidance published by the Commissioner (NHSE) on roving and mobile models must be followed if consent is provided by the Commissioner (NHSE).
- 7.6 Any amendments, additions or removal of Designated Sites shall be undertaken in accordance with the Designation Process.
- 7.7 Where the Commissioner (NHSE) requires the GP practices to put into place any reasonable security requirements regarding the vaccine and the Designated Site, the GP practice shall make all reasonable efforts to ensure that these requirements are put into place as soon as possible.

- 7.8 GP practices and the PCN groupings they each work within must ensure that Designated Sites and the vaccination clinics are operated in accordance with the Designation Process and any other criteria published alongside this ES specification.
- 7.9 GP practices must inform the Commissioner (NHSE) immediately if, for any reason, a Designated Site ceases to meet the criteria set out in this ES and the Commissioner (NHSE) reserves the right to require a GP practice to withdraw from this ES, in accordance with the withdrawal criteria at paragraph 12.33.

8 Sub-contracting Arrangements

- 8.1 The Commissioner (NHSE) acknowledges that to deliver the services pursuant to this ES, a GP practice may require the ability to sub-contract the delivery of the required clinical services to another GP practice in the PCN grouping or another party. Where a GP practice is considering sub-contracting arrangements related to the provision of services under the ES, the GP practice must comply with the requirements set out in the statutory regulations or directions that underpin its primary medical services contracts in relation to sub-contracting, which will also apply to any arrangements to sub-contract services under the ES.
- 8.2 GP practices and their PCN grouping must make available, on request from the Commissioner (NHSE), any reasonable information relating to the sub-contracting arrangements and reporting information relating to the delivery of ES.
- 8.3 Insofar as the sub-contracting of the clinical services pursuant to this ES is necessary to deliver these services and is compliant with the primary medical services legal and contractual requirements, the Commissioner (NHSE) will not object to the sub-contracting.

9 Service Delivery Specification

- 9.1 Subject to paragraph 9.5, the GP practice must make arrangements to vaccinate Patients in:
- 9.1.1 JCVI cohort (i) (eligible patients resident in an older adult care home) [within 10 weeks or as soon as reasonably possible²];
- 9.1.2 JCVI cohort (ii) (severely immunosuppressed patients as defined in the Green Book); and

² To be updated following publication of final JCVI advice

9.1.3 JCVI cohort (iii) (housebound patients);

following a JCVI announcement and subject to clinical guidelines on the interval between doses.

9.2 The GP practice may vaccinate those Patients, other than those in JCVI cohort (i) following a JCVI announcement where the Patient also fulfils one of the following criteria:

- (a) whose name is included on the GP practice's registered patient list;
- (b) is an unregistered patient; or
- (c) is registered on another primary medical services practice's list of registered patients but has chosen to receive their vaccination from the PCN grouping.

9.3 [The GP practice may vaccinate those Patients who:

9.3.1 were previously eligible to receive vaccination but who chose not to take up the offer or were unable to take up the offer and meet the eligibility criteria set out by JCVI to receive vaccination; or

9.3.2 were previously not eligible to receive vaccination but now meet the eligibility criteria set out by JCVI to receive vaccination.]

9.4 Patients do not require an NHS number or GP registration to receive a vaccination and should not be denied vaccination on this basis.

9.5 GP practices must liaise with their own and where appropriate other Primary Care Networks which are responsible for delivery of the Enhanced Health in Care Homes provisions in the Network Contract Directed Enhanced Service, to ensure that a joined up service is delivered to all PCN-linked Care Homes to be served by the relevant PCN.

9.6 GP practices must ensure:

9.6.1 that, in addition to any national call/re-call service, they write, text or call Patients (as appropriate) to support high uptake of vaccinations and minimise wastage;

- 9.6.2 that they actively co-operate with any national call/re-call service requirements including where GP practices are not being requested to administer vaccinations to Patients during a Pause;
- 9.6.3 that they maintain clear records of how they have contacted (including 'called' and recalled) Patients;
- 9.6.4 that vaccinations are administered during the period of this ES;
- 9.6.5 that all Patients who receive vaccinations are eligible under the cohorts and suitable clinically in accordance with law and guidance;
- 9.6.6 that informed Patient consent is obtained by a registered healthcare professional and the Patient's consent (or refusal of consent, where relevant) to the vaccination (or the name of the person who gave (or refused) consent to the vaccination and that person's relationship to the Patient) must be recorded in the Point of Care System and in accordance with law and guidance;
- 9.6.7 Patient consent obtained in accordance with paragraph 9.6.6 is recorded (as appropriate) for any necessary information sharing with the Commissioner (NHSE) in accordance with data protection law and guidance;
- 9.6.8 that they comply with all relevant clinical checklists published by NHS England (including checklists relevant to the vaccination of those under 18 years of age);
- 9.6.9 that they comply with the Standard Operating Procedures relating to delivery of local vaccination services and continue to meet the designation criteria as set out in the Designation Process;
- 9.6.10 that vaccinations are provided in line with guidance in immunisation against infectious disease (The Green Book), and GP practices have a process in place to check any updates to the Green Book;
- 9.6.11 that they comply with all relevant guidance issued by JCVI, the Commissioner (NHSE), MHRA and/or UKHSA. (In the event of a conflict between guidance issued by these organisations, NHS England shall confirm which guidance shall be adopted);
- 9.6.12 that they provide to each Patient being administered a vaccine the vaccination information as directed by the Commissioner (NHSE), which

may include a printed copy of the manufacturer's patient information leaflet about the vaccine (which would be provided to GP practices) and any other relevant information. Practices should advise Patients where required of any current policy as recommended by the JCVI and as set out at paragraph 9.6.9(b) 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.

- 9.7 GP practices are not required to offer call/re-call to care home residents, Patients in a residential setting for whom it has been agreed with the Commissioner (NHSE) that they should receive their vaccinations in a residential setting rather than a vaccination site, and frontline health and social care workers. Where these Patients are easily identifiable, GP practices may wish to offer call/re-call.
- 9.8 The GP practice must ensure the Patient has understood that failure to receive all recommended doses of the vaccine may render the vaccination ineffective (where appropriate) and should ensure that a follow up appointment to receive any subsequent dose has been booked, acknowledging that in exceptional circumstances appointments may need to be moved.
- 9.9 The GP practice, in collaboration with other GP practices in the PCN grouping, may be required to operate regular clinics in the evenings, at the weekends and on bank holidays 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 number of vaccines the GP practice is able to deliver, JCVI guidance on dosing intervals, the size of the local population eligible for vaccination and available vaccine supply.
- 9.10 The Commissioner (NHSE) shall not object to the delivery of the ES during extended hours where this does not negatively impact on the core primary care offer or the GP practice is able to demonstrate that the equivalent extended hours are provided at an alternative time for the convenience of patient access.
- 9.11 The GP practice must ensure that they have in place suitable arrangements to prevent the disruption of other services or obligations on GP practice under its primary care contract.
- 9.12 All persons involved in the administration of the vaccine must have:
 - 9.12.1 completed the additional online COVID-19 specific training modules available on the e-learning for health website when available. GP

practices will be expected to oversee and keep a record to confirm that all staff have undertaken the training prior to participating in the administration of vaccinations. This includes any additional training associated with new vaccines that become available during the period of this ES;

- 9.12.2 the necessary experience, skills and training to administer vaccines in general, including completion of the general immunisation training available on e-learning for health and face-to-face administration training, where relevant;
- 9.12.3 the necessary experience, skills and training, including training with regard to the recognition and initial treatment of anaphylaxis;
- 9.12.4 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), a Disclosure and Barring Service (DBS) certificate; and
- 9.12.5 where a healthcare professional is administering the vaccine:
 - (a) read and understood the clinical guidance available and to be published on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/>;
 - (b) understood and be familiar with the Patient Group Directions for the COVID-19 vaccines^{3,4} made available by UKHSA and authorised by the Commissioner (NHSE) including guidance on who can use them <https://www.gov.uk/government/publications/patient-group-directions-pgds/patient-group-directions-who-can-use-them>; and
 - (c) ensured that registered healthcare professionals were involved in the preparation (in accordance with the manufacturer's instructions) of the vaccine(s) unless unregistered staff have been trained to do this; and

³ <https://www.england.nhs.uk/coronavirus/publication/patient-group-direction-for-covid-19-mrna-vaccine-bnt162b2-pfizer-biontech/>

⁴ <https://www.england.nhs.uk/coronavirus/publication/patient-group-direction-for-covid-19-vaccine-astrazeneca-chadox1-s-recombinant/>

9.12.6 where any other persons are administering the vaccine:

- (a) be authorised, listed, referred to or otherwise identified by reference to The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020;
- (b) while preparing and/or administering vaccinations be supervised by a healthcare professional fulfilling the requirements of paragraph 9.12.4 above; and
- (c) be familiar with, understand and act within the scope of the national protocol for the COVID-19 vaccines⁵, made available by the UKHSA and approved by the Secretary of State for Health and Social Care.

9.13 GP practices must ensure that they are familiar with all guidance relating to the administration, handling and storage of the different types of vaccine. GP practices must also ensure that they are assured to administer all adult vaccine types as required by the Commissioner (NHSE).

9.14 GP practices must ensure that all vaccines are received, stored, prepared and subsequently transported (where appropriate) in accordance with the relevant manufacturer's⁶, the UKHSA's⁷ and NHS England's instructions and all associated Standard Operating Procedures, including that all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that the readings are taken and recorded from that thermometer on all working days and that appropriate action is taken when readings are outside the recommended temperature.

9.15 Where vaccinations are administered away from a Designated Site (for example, at a care home), the GP practice must ensure that appropriate measures are taken to ensure the integrity of the cold chain, following any guidance issued by JCVI or the UKHSA. 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.

⁵ <https://www.gov.uk/government/publications/national-protocol-for-covid-19-mrna-vaccine-bnt162b2-pfizerbiontech>

⁶ Information from the manufacturer suggests that there will be very specific handling requirements to preserve stability. Vaccines will require 2-8c storage on-site

⁷ UKHSA (previously PHE's) ordering, storing and handling protocol
<https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines>

- 9.16 GP practices should ensure that 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 using this ES due to a protected characteristic, as outlined in the Equality Act (2010) – this includes Age, Disability, Gender Reassignment, Marriage and Civil Partnership, Pregnancy and Maternity, Race, Religion or Belief, Sex or Sexual Orientation.
- 9.17 The Commissioner (NHSE) may be able to provide support to PCN groupings by way of equipment loan. Where such support is made available, all equipment will be maintained by the GP practices and shall be returned to the Commissioner (NHSE) at the end of the delivery of services under this ES.

10 Monitoring and Reporting

- 10.1 GP practices delivering this ES must have signed up to receive the Primary Care Bulletin and ensure they receive the Vaccination Site Bulletin published by the Commissioner (NHSE) so key information in relation to the delivery of this ES can be communicated in a timely manner.
- 10.2 GP practices and PCN groupings must monitor and report all activity information in accordance with the monitoring and reporting standards as published by the Commissioner (NHSE). This includes guidance published by the Commissioner (NHSE) on the recording of COVID-19 vaccination appointments to ensure consistent national data captures.
- 10.3 GP practices must adhere to defined standards of record keeping ensuring that the vaccination event is recorded the same day that it is administered within the Point of Care System and all mandatory fields are completed accurately. GP practices 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.
- 10.4 Point of Care systems will not permit GP practices to record the entry of a vaccination event after 7 days following the vaccination event. GP practices must refer any cases which require recording after 7 days following the vaccination event to the Vaccination Data Resolution Service (VDRS) team of the Commissioner (NHSE) for action. The item of service fees and any associated supplements as set out at paragraph 11 shall not be claimed in relation to records referred to VDRS.

- 10.5 GP practices operating within the PCN grouping:
- 10.5.1 must only enter new vaccinations into one approved 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 (NHSE); or
 - (b) subject to paragraph 10.4, where it is necessary to include amendments to vaccination events previously recorded.
- 10.5.2 are 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 (NHSE).
- 10.6 GP practices will be 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. GP practices will be expected to follow MHRA incident management processes in the case of a severe reaction.9.6A

11 Payment and Validation⁸

- 11.1 Subject to compliance with this ES, a payment of:
- 11.1.1 £10.06 shall be payable to the GP practice for administration of each vaccination to each Patient; and
- 11.1.2 £10.00 shall be payable to the GP practice for administration of each vaccination to each Patient where:
- (a) the medical condition of a Patient is such that, in the reasonable opinion of the 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;

⁸ For further information on payments please see the PCN Finance and Payments Guidance available here: https://future.nhs.uk/P_C_N/view?And objectId=88259013

- (b) where that Patient requires administration of a vaccination; and
- (c) where the GP practice has recorded the status of the Patient in the Point of Care System prior to making the claim for payment.

11.2 GP practices must ensure that:

11.2.1 the Patient who received the vaccination(s) was a Patient at the time the vaccine was administered, and all of the following apply (except where the claim for reimbursement is for a qualifying exception):

- (a) the GP practice has used a vaccine supplied in accordance with the COVID-19 vaccination programme;
- (b) the Patient in respect of whom payment is being claimed was within an announced and authorised cohort at the time the vaccine was administered;
- (c) the vaccination has been recorded on the Point of Care System on the day of the administration of the vaccination to the Patient; and
- (d) the GP practice has not received and does 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 and/or under their COVID-19 ES Vaccination Collaboration Agreement) in respect of the vaccine or vaccination; and

11.2.2 the Patient's vaccinations have been administered by the GP practice's PCN grouping.

11.3 GP practices must make arrangements within their PCN grouping for payments in respect of:

11.3.1 unregistered patients;

11.3.2 patients without an NHS number;

11.3.3 patients registered on another primary medical services practice's list of registered patients, or the primary medical services provider is a Defence Medical Services practice commissioned by the Ministry of Defence;

11.3.4 frontline health and social care workers; and/or patients in a residential setting who are registered on another primary medical services practice's list of patients, but who have elected to receive the vaccination from the GP practice for convenience;

and who fall within the definition of Patient and who are vaccinated at the PCN grouping's Designated Site.

11.4 GP practices must nominate a single GP practice within the PCN grouping to claim and receive (on their own behalf) payment for these unregistered patients, frontline health and social care workers and patients in a residential setting which shall be set out in the COVID-19 ES Vaccination Collaboration Agreement.

11.5 GP practices must make arrangements within their PCN grouping for the nomination of a host GP practice for the PCN grouping which will receive payments due under this ES for and on behalf of the GP practice. This is necessary as existing systems are unable to support payment in a timely manner and to facilitate the payment system for this novel and complex situation where vaccination of the population across multiple locations and settings is required. The PCN grouping should ensure that arrangements are in place so that the correct ODS code is entered to enable payment to the host GP practice. The host GP practice will then receive data which enables it to identify how many Patients on the GP practice's list of registered patients have been vaccinated, for verification and the transfer of funds to the GP practice. Payment arrangements may be reviewed in line with subsequent developments to IT systems. Any changes to the host practice must be notified to the Commissioner (NHSE) providing no less than 10 days' notice of the change and cannot be made retrospectively.

11.6 GP practices must submit a claim to the Commissioner for payment before the end of the period of 3 months beginning on the final day of the month in which completion of administration of the vaccination to which the payment relates occurred. This requirement is necessary due to the high volume of vaccinations being delivered under this ES and to ensure timely post payment verification which is necessary to ensure correct payments to PCN groupings and dissemination to GP practices.

11.7 Payment under this ES, or any part thereof, is conditional on the GP practice satisfying the following:

11.7.1 entering into this ES, including any variations and updates;

- 11.7.2 having in place a COVID-19 ES Vaccination Collaboration Agreement that complies with the requirements of paragraph 6.5;
 - 11.7.3 they comply (and maintain compliance) with the requirements of this ES;
 - 11.7.4 they make available to the Commissioner (NHSE) any information under this ES which the Commissioner (NHSE) needs and the GP practice either has or could be reasonably expected to obtain;
 - 11.7.5 they make any returns (including payment claims as required by paragraph 11.6) or provide any information reasonably required by the Commissioner (NHSE) (or on the Commissioner's behalf) (whether computerised or otherwise) to support payment and do so promptly and fully; and
 - 11.7.6 ensuring that all information supplied pursuant to or in accordance with this paragraph 11 is accurate.
- 11.8 If the GP practice does not satisfy any of the above conditions, the Commissioner (NHSE) may withhold payment of any, or any part of, an amount due under this ES that is otherwise payable.
- 11.9 Practices may not claim payment for Patients vaccinated outside of the PCN grouping (for example, at a vaccination centre).
- 11.10 If the Commissioner (NHSE) makes a payment to a GP practice under this ES and:
- 11.10.1 the GP practice 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 (including where a payment on account overestimates the amount that is to fall due);
 - 11.10.2 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
 - 11.10.3 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 GP practice, and where no such deduction can be made, it is a condition of the payments made under this ES that the contractor under its General Medical Services contract, Personal

Medical Services agreement or Alternative Provider Medical Services contract (as relevant) must pay to the Commissioner (NHSE) that equivalent amount.

- 11.11 Where the Commissioner (NHSE) is entitled under this ES to withhold all or part of a payment because of a breach of a payment condition, and the Commissioner (NHSE) does so or recovers the money by deducting an equivalent amount from another payment in accordance with this ES, it may, where it sees fit to do so, reimburse the GP practice the amount withheld or recovered, if the breach is cured.
- 11.12 The GP practice must comply with any reasonable requests to facilitate post payment verification. This may include auditing claims to ensure that they meet the requirements of this ES.
- 11.13 The Commissioner (NHSE) may make additional discretionary payments available to GP practices to support the delivery of or incentivise vaccinations, in particular underserved groups in exceptional circumstances. Details of those additional payments, will be made available on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/primary-care-guidance/>.

12 Variations To and Subsequent Withdrawal From this ES

- 12.1 Variations to this ES will be published on <https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/primary-care-guidance/> and will take effect immediately on publication. GP practices will also be notified of any changes via the Vaccination Site Bulletin.
- 12.2 In order to simplify the participation process, where there are any variations to this ES after 14 July 2022, the GP practice which has indicated its willingness to participate in this ES and the Commissioner (NHSE) is assured that the GP practice has the capacity to deliver this ES alongside their existing contractual requirements (and in compliance with any published guidance), will automatically be enrolled.
- 12.3 If a GP practice cannot meet the requirements of this ES it must withdraw from this ES by serving written notice on the Commissioner (NHSE) to that effect with supporting reasons as to why it cannot meet the revised requirements, such notice must be received by the Commissioner (NHSE) no later than 42 days after publication of the relevant variation and providing no less than 42 days' notice of the GP practice's withdrawal. The GP practice will also need to make

the necessary amendments to the COVID-19 ES Vaccination Collaboration Agreement.

- 12.4 Following notice of their intention to withdraw from the ES, but prior to the actual withdrawal date, GP practices must comply with their COVID-19 ES Vaccination Collaboration Agreement and co-operate with their PCN grouping during and following their withdrawal from this ES.
- 12.5 The provisions of Annex A will apply to practices that withdraw from this ES.

Annex A: Provisions relating to GP practices that terminate or withdraw from this ES (subject to the provisions below for termination attributable to a GP practice formation or merger) and new GP practices

- 1 Where a GP practice has entered into this ES but its primary medical services contract subsequently terminates or the GP practice withdraws from this ES prior to the end of this ES, the GP practice is entitled to a payment in respect of its participation if such a payment has not already been made, in accordance with the provisions set out below. Any payment will fall due on the last day of the month following the month during which the GP practice provides the information required.
- 2 In order to qualify for payment in respect of participation under this ES, the GP practice must comply with and provide the Commissioner (NHSE) with the information in this ES specification or as agreed with the Commissioner (NHSE) before payment will be made. This information should be provided in writing within 28 days following the termination of the contract or the GP practice's withdrawal from this ES.
- 3 The payment due to a GP practice whose primary medical services contract subsequently terminates or withdraws from this ES prior to the end of this ES will be based on the number of completed vaccinations provided to Patients, prior to the termination of the primary medical services contract or withdrawal from this ES.

Provisions relating to GP practices who merge or are formed

- 4 Where two or more GP practices merge or a new primary medical services contract is awarded and as a result two or more lists of registered patients are combined, transferred (for example from a terminated practice) or a new list of registered patients is developed, the new GP practice(s) may enter into a new or varied arrangement with the Commissioner (NHSE) to provide this ES.
- 5 In the event of a practice merger, the ES arrangements of the merged GP practices will be treated as having terminated (unless otherwise agreed with the Commissioner (NHSE)) and the entitlement of those GP practice(s) to any payment will be assessed on the basis of the provisions of paragraph 11 of this ES.

- 6 The entitlement to any payment(s) of the GP practice(s), formed following a practice merger, entering into the new or varied arrangement for this ES, will be assessed and any new or varied arrangements that may be agreed in writing with the Commissioner (NHSE) will begin at the time the GP practice(s) starts to provide this ES under such arrangements.
- 7 Where that new or varied arrangement is entered into and begins within 28 days of the new GP practice(s) being formed, the new or varied arrangements are deemed to have begun on the date of the new GP practice(s) being formed and payment will be assessed in line with this ES specification as of that date.
- 8 Where the GP practice participating in the ES is subject to a practice merger and:
- 8.1 the application of the provisions set out above in respect of practice mergers would, in the reasonable opinion of the Commissioner (NHSE), lead to an inequitable result; or,
- 8.2 the circumstances of the split or merger are such that the provisions set out above in respect of practice mergers cannot be applied,
- the Commissioner (NHSE) may, in consultation with the GP practice or GP practices concerned, agree to such payments as in the Commissioner's (NHSE) opinion are reasonable in all of the circumstances.

New contract awards

- 9 Where a new primary medical services contract is awarded by the Commissioner (NHSE) after the commencement of this ES, the GP practice will be offered the ability to opt-in to the delivery of this ES where it is able to join a PCN grouping.