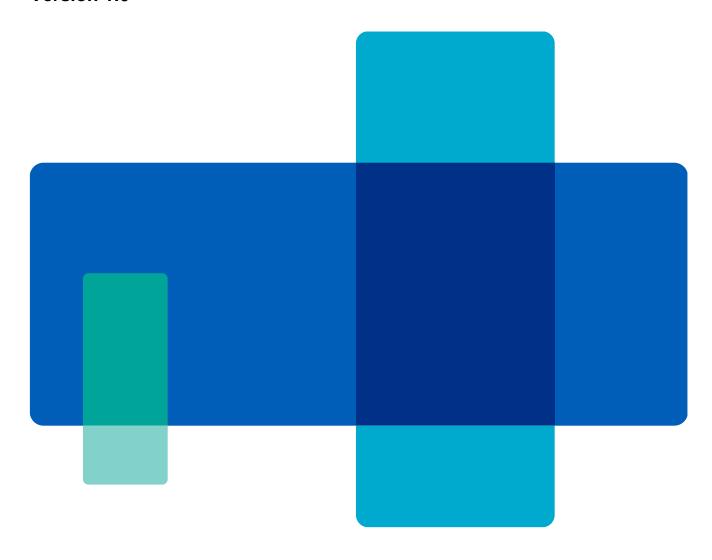
Classification: Official



General Practice Outreach Enhanced Service Specification

COVID-19 vaccination programme: 1 April 2025 to 31 March 2026

Version 1.0



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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."

1. Introduction

- 1.1. The Practice has submitted a Tender Response Document and has been awarded this arrangement to provide Vaccination Outreach Services and the adminstration of vaccinations in accordance with this Enhanced Service (ES¹). This ES is subject to amendments from time to time as the COVID-19 vaccination programme develops and is subject to Ministerial Decision.
- 1.2. This ES is a core national specification setting out minimum requirements that should not be varied locally. The tender response document for the local [procurement exercise], however, reflects the specific needs of that area that the Practice's services will meet.
- 1.3. This ES is designed to cover enhanced aspects of vaccination awareness, education and delivery, 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.
- 1.4. A key aim of this ES is to maximise vaccination awareness and education through outreach services and, as a consequence of this, build trust in vaccinations and maximise the uptake of COVID-19 and seasonal influenza vaccinations (together with other vaccinations for which the Patient is eligible). The services are to be provided from a variety of settings and effectively utilise available staff across healthare providers.
- 1.5. Practices can advise the Patient 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 or guidance. This should include signposting to other vaccinations where, if eligible, the Patient indicates that they have not made arrangements for the vaccination and the Patient does not elect or it is not possible to have a co-administered vaccination (where the Practice is able to offer this).

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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. NHS England is responsible and accountable for the discharge of all the Section 7A functions. This agreement cannot be changed or varied locally.

- 1.6. A Practice need not be a member of an established Primary Care Network (PCN) or an established PCN Grouping to participate in this ES and may form an alternative PCN Grouping to deliver this ES. Practices which are not a Single Practice PCN are expected to collaborate with neighbouring Practices in a PCN Grouping to deliver this ES. All collaborating Practices are expected to sign up to a COVID-19 Outreach ES Vaccination Collaboration Agreement as described in this ES.
- 1.7. Where this ES sets out a requirement or obligation of a PCN Grouping, each Practice is responsible for ensuring the requirement or obligation is carried out on behalf of that PCN Grouping. Where this ES is entered into by a Single Practice PCN, that Practice is responsible for ensuring the requirement or obligation of the PCN Grouping is carried out.
- 1.8. The Practice agrees to provide this ES, including any variations and updates from the Commencement Date until the End Date, unless terminated earlier in accordance with the terms of this ES.
- 1.9. By agreeing to deliver this ES, the 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 Practice's primary medical services contract.

2. Definitions

- 2.1. This specification is referred to as this "ES".
- 2.2. In this ES:
 - 2.2.1. "Commencement Date" means [1 April 2025];
 - 2.2.2. "Commissioner" means NHS England;
 - 2.2.3. "COVID-19 Outreach ES Vaccination Collaboration Agreement" means the agreement entered into by collaborating Practices and which incorporates the provisions that are required to be included in a COVID-19 Outreach ES Vaccination Collaboration Agreement in accordance with paragraph 5.7;
 - 2.2.4. "CQC" means the Care Quality Commission;
 - 2.2.5. "**Designated Site**" means the premises nominated by the PCN Grouping and approved by the Commissioner in accordance with

- the Designation Process as the premises to which the COVID-19 vaccine will be delivered and where the COVID-19 vaccine must be stored overnight.;
- 2.2.6. "Designation Process" means the COVID-19 Assurance and Site Designation process set out in the COVID-19 vaccination programme: 1 April 2025 to 31 March 2026 Site Sign-up Process for Suppliers document 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 ES;
- 2.2.7. "End Date" means [31 March 2026] unless terminated earlier in accordance with paragraph 3.12 or otherwise in accordance with this ES or extended in accordance with paragraph 3.2;
- 2.2.8. "Expected COVID-19 Vaccination Administration
 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;
- 2.2.9. "GPhC" means the General Pharmaceutical Council:
- 2.2.10. "Green Book" means 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;
- 2.2.11. "Healthcare Premises" means any location that falls into one or more of these categories:
 - 2.2.11.1. a place to which people are admitted for the purpose of receiving a regulated activity to meet healthcare needs (for example a hospital, day surgery unit);
 - 2.2.11.2. a place in which people live as their main or sole place of residence or in which they are educated, and they receive care or treatment there (for example, a care home);

- 2.2.11.3. an urgent care facility (for example, a walk-in centre);
- 2.2.11.4. the premises where a primary care provider carries on regulated activity other than vaccinations (for example a GP, pharmacy, out-of-hours, dental, community substance misuse service or sexual assault referral centre);
- 2.2.11.5. the premises from which a registered provider organises or manages care that is delivered to people in their homes (for example a domiciliary care (home care), supported living or shared lives service);
- 2.2.11.6. a place from where an ambulance or patient transport service is managed;
- 2.2.11.7. a stand-alone permanent diagnostic or screening facility; or
- 2.2.11.8. a place from where urgent remote clinical advice and triage is managed (for example, an NHS 111 service);
- 2.2.12. "**JCVI**" means the Joint Committee on Vaccination and Immunisation:
- 2.2.13. "JCVI Cohorts" means the cohorts of Patients referenced by JCVI advice;
- 2.2.14. "MHRA" means the Medicines and Healthcare products Regulatory Agency;
- 2.2.15. "Ministerial Decision" means a decision issued by the Secretary of State for Health and Social Care:
- 2.2.16. "National Booking Service" or "NBS" means the national system used by Patients to book coronavirus (COVID-19) vaccination appointments;
- 2.2.17. "Patient" means those patients eligible to receive the vaccination by their inclusion in a JCVI Cohort which has been announced and authorised by the Commissioner as eligible for vaccination by the Practice (through its PCN Grouping) and as set out at paragraph 7;

- 2.2.18. "Pause" means a pause to the requirement for the administration of COVID-19 vaccinations and the Vaccination Outreach Services as set out at paragraph 3.7;
- 2.2.19. "PCN Grouping" means the group of collaborating Practices which together submitted a Tender Response Document and collaborate to deliver the services in accordance with this ES and additional neighbouring Practices and/or other groups of Practices working together. They must do so under a COVID-19 Outreach ES Vaccination Collaboration Agreement;
- 2.2.20. "Point of Care System" means a clinical system that has been assured by the Commissioner to record COVID-19 vaccination events;
- 2.2.21. "Private Patients" means any non-NHS Patients;
- 2.2.22. "Practice" means 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 submitted a Tender Response Document, been awarded and has agreed with the Commissioner to deliver this ES:
- 2.2.23. "Primary Care Network" or "PCN" means a network of primary medical services contractors which has been approved by NHS England, under the Network Contract Directed Enhanced Service, serving an identified geographical area;
- 2.2.24. "Seasonal Influenza ES" means the Seasonal Influenza Vaccination Programme Enhanced Service Specification for 2025/26 which is capable of being entered into by the Practice during the Term;
- 2.2.25. "**SFE**" means the NHS General Medical Services Statement of Financial Entitlements Directions (as amended from time to time);
- 2.2.26. **"Single Practice PCN"** means a single primary medical services contractor which has been approved by the Network Contract Directed Enhanced Service, serving an identified geographical area;
 - 2.2.27. **"Tender Response Document"** means the response to the COVID-19 Vaccination Site Selection Process Guidance whereby

- the Practice is awarded this arrangement to deliver services under this ES:
- 2.2.28. **"Term"** means the period from the Expected COVID-19 Vaccination Administration Commencement Date to the End Date;
- 2.2.29. "UKHSA" means the UK Health Security Agency;
- 2.2.30. "Vaccination Outreach Services" means the services as described at paragraph 7.1; and
- 2.2.31. "Vaccination Outreach Services Commencement Date" means [insert date].
- 2.3. In this ES words importing the singular include the plural and vice versa.
- 2.4. References to any body, organisation or office include reference to its applicable successor from time to time.

3. Duration

- 3.1. The Practice shall provide this ES in accordance with its terms from the Commencement Date to the End Date unless it is terminated in accordance with paragraph 3.12.
- 3.2. The Commissioner may, on no less than 21 days notice to the Practice and no later than 21 days before the End Date, agree with the Practice to extend the term by up to 12 months.
- 3.3. The Vaccination Outreach Services shall commence with effect from Vaccination Outreach Services Commencement Date.
- 3.4. The administration of COVID-19 vaccinations shall commence with effect from the Expected COVID-19 Vaccination Administration Commencement Date.
- 3.5. Where the Practice, together with the other Practices in the PCN Grouping, is unable to commence the Vaccination Outreach Service by the Vaccination Outreach Services Commencement Date, the Practice must notify the Commissioner as soon as reasonably possible.
- 3.6. The Commissioner may agree with the Practice, together with the other Practices in the PCN Grouping, an extension not exceeding 2 weeks following the Vaccination Outreach Services Commencement Date to

- commence the Vaccination Outreach Services. Failure to begin the Vaccination Outreach Services within the agreed timeframe will result in termination of the ES on a date to be notified by the Commissioner to the Practice.
- 3.7. 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, the arrangements do not represent acceptable value for money and/or the Commissioner determines that there is no longer need for the Vaccination Outreach Services, the Commissioner may require the Practice together with the other Practices in the PCN Grouping to suspend the COVID-19 vaccination services (a "Pause").
- 3.8. Where the Practice together with the other Practices in the PCN Grouping do 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, the arrangements acceptable value for money and/or there is need for the Vaccination Outreach Service and the Commissioner shall, acting reasonably, reconsider whether it remains appropriate to continue with the Pause.
- 3.9. During a Pause, the Practice shall not administer COVID-19 vaccinations and/orshall not provide the Vaccination Outreach Services 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.
- 3.10. While the services are Paused the Commissioner and the Practice shall use all reasonable efforts to ensure that no further Patients are referred to the Practices within the PCN Grouping for the services under this ES and should direct Patients to available services, as appropriate.
- 3.11. It is a condition of this ES that the Practice must also deliver each Seasonal Influenza ES available during the Term. The offer of coadministration of the COVID-19 and seasonal influenza vaccinations, subject to vaccine availability, must be made to each eligible Patient the Practice is able to vaccinate in accordance with the Seasonal Influenza

- ES, this ES and recommendations for co-administration in the Green Book.
- 3.12. This ES may be terminated on any of the following events:
 - 3.12.1. automatically when the COVID-19 vaccination programme or the outreach programme comes to an end (and which shall be announced by the Commissioner);
 - 3.12.2. automatically where the Practice has not offered vaccinations under the Seasonal Influenza ES for the preceding 56 days or otherwise agreed by the Commissioner and unless the seasonal influenza vaccination programme has come to an end (as set out in the Seasonal Influenza ES);
 - 3.12.3. automatically on the same date as the termination of the Practice's Seasonal Influenza ES, where the termination of the Seasonal Influenza ES is by the Commissioner or the Practice on notice;
 - 3.12.4. by the Commissioner providing not less than 42 days' written notice to the Practice:
 - 3.12.5. by the Practice providing not less than 42 days' written notice to the Commissioner, unless otherwise agreed with the Commissioner:
 - 3.12.6. immediately where the Practice does not commence the Vaccination Outreach Services and/or the administration of vaccinations in accordance with paragraph 3.3 to 3.6;
 - 3.12.7. automatically on the same date as the termination of the Practice's primary medical services contract; or
 - 3.12.8. automatically, where a single Practice which has been operating as a Single Practice PCN no longer fulfills the definition of a Single Practice PCN.
- 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/.

4. Vaccine supply and availability

- 4.1. The Practice, through its PCN Grouping, will be provided with COVID-19 vaccines to deliver this ES. The vaccine must not be used to administer vaccinations to Private Patients. The Practice and the Commissioner may agree to the vaccination or prioritisation of particular JCVI Cohorts.
- 4.2. The Practice should understand that the COVID-19 vaccine availability and supply may be challenging and may be constrained and is subject to change over time.
- 4.3. The Commissioner may (acting reasonably) need to make allocation decisions regarding the COVID-19 vaccine during the Term of this ES. Allocation decisions could include prioritising providers or the use of a particular type of COVID-19 vaccine.
- 4.4. 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 vaccination delivery as set out at paragraph 4.1.
- 4.5. The Practice must provide support in relation to stock forecasting, use and ordering of COVID-19 vaccine as requested by the Commissioner.
- 4.6. The Practice must minimise COVID-19 vaccine wastage including through how activity is planned and support the high uptake of vaccinations where possible through the provision of the Vaccination Outreach Services.
- 4.7. Collaborating Practices in the PCN Grouping shall be considered joint and several owners of the COVID-19 vaccine which may be shared and governed in accordance with the agreement between them and which must be documented in the COVID-19 Outreach ES Vaccination Collaboration Agreement.

5. Collaboration requirements and PCN Groupings

- 5.1. Subject to paragraph 5.11, the 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. The Practice will:

- 5.2.1. comply with any reasonable request for information from the Commissioner relating to the provision of the services pursuant to this ES:
- 5.2.2. have regard to all relevant guidance published by the Commissioner or referenced within this ES;
- 5.2.3. comply with all clinical protocols giving explicit consideration to contra-indications and any guidance around concurrent adminstration 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 ES, including information on how to access the services and any changes to them;
- 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;
- 5.2.6. 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, in a timely and effective way and give to each 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; and
- 5.2.7. openly, honestly and efficiently share information with other relevant parties including the 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.
- 5.3. The Practice must work in its PCN Grouping to co-ordinate and deliver the Vaccination Outreach Services and the administration of vaccinations in line with the requirements set out in this ES.
- 5.4. 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) and regulation 3(5), (8) and (9) respectively of the Human Medicines Regulations 2012 (as amended).

- 5.5. The Practice is expected to participate in relevant PCN Grouping meetings relating to the COVID-19 vaccination programme, in so far as is reasonable.
- 5.6. The Practice must ensure that it collaborates with other Practices in the PCN Grouping and have nominated (through the Tender Response Document) a Designated Site for acceptance of delivery of the COVID-19 vaccines under this ES and in accordance with their Tender Response Document.
- 5.7. Collaborating Practices must have in place a COVID-19 Outreach ES Vaccination Collaboration Agreement signed by all collaborating Practices in its PCN Grouping by no later than the day prior to the Commencement Date or such other date as may be agreed by the Commissioner that sets out the governance and clinical delivery model (i.e. how clinics are delivered and responsibility is shared between the Practices within the PCN Grouping), deployed by the PCN Grouping and as a minimum contains additional provisions in relation to the following:
 - 5.7.1. appropriate records of the Vaccination Outreach Services which shall be more particularly agreed with the Commissioner;
 - 5.7.2. appropriate arrangements for Patient record sharing in line with data protection legislation, including to enable Practices to access information on the name and the manufacturer of any COVID-19 vaccinations previously received by the Patient;
 - 5.7.3. appropriate arrangements for reporting of COVID-19 activity data, vaccine stock (to include stock use and stock forecasting which must include the brand of COVID-19 vaccine delivered and required by the PCN Grouping), available capacity and submission of required data to the Commissioner;
 - 5.7.4. appropriate arrangements for communicating with Patients;
 - 5.7.5. 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;
 - 5.7.6. financial arrangements between the collaborating Practices on how Practices will share payment received by the host Practice in accordance with paragraph 14.7 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;
- 5.7.7. arrangements in relation to use of the Designated Site (for vaccine delivery only) and any other relevant premises (as required);
- 5.7.8. sub-contracting arrangements (as required);
- 5.7.9. a lead contact email address for the PCN Grouping which shall be supplied to the Commissioner for use in disseminating information urgently;
- 5.7.10. appropriate indemnity arrangements. The Clinical Negligence Scheme for General Practice (CNSGP) provides clinical negligence indemnity cover for all staff engaged by a 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 Practice's registered patients so would apply to the provision of any NHS COVID-19 vaccinations by a Practice to a person, including where they are not on the list of registered patients of that Practice;
- 5.7.11. appropriate arrangements to ensure that the Practice can identify, if appropriate, which Patients receive Vaccination Outreach Services and vaccinations under this ES; and
- 5.7.12. the arrangements as between the collaborating Practices for the co-administration of the COVID-19 vaccination and the seasonal influenza vaccination. Co-administration shall at all times be in line with the provisions set out in the Green Book and JCVI guidance.
- 5.8. The Commissioner has published a template COVID-19 Outreach ES Vaccination Collaboration Agreement on https://www.england.nhs.uk/coronavirus/covid-19-vaccination-programme/primary-care-guidance/, which collaborating Practices may wish to use and adapt for the purpose of delivering this ES.
- 5.9. The Practice, through its PCN Grouping, 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 PCN Groupings providing weekly updates on actual COVID-19 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. PCN Groupings will need to submit information using a specified national system. Stock availability may be linked to the forecasted number of eligible patients locally.

- 5.10. PCN Groupings will need to plan service vaccination delivery arrangements in line with COVID-19 stock forecasting and ordering arrangements including:
 - 5.10.1. planning Vaccination Outreach Services and clinics for the administration of vaccinations according to expected vaccine supply;
 - 5.10.2. coordinating required trained staff;
 - 5.10.3. ordering required consumables including COVID-19 vaccine supply within required timeframes to ensure service continuity;
 - 5.10.4. receiving and safely storing supplies;
 - 5.10.5. amending clinic schedules if there is a disruption to supply and undertaking timely communication of any changes to Patients; and
 - 5.10.6. maximising the opportunities for co-administration of the COVID-19 vaccination and the seasonal influenza vaccination, in order to maximise efficiency for the Practice and minimise the number of attendances required for Patients to receive these vaccinations.
- 5.11. The requriements to collaborate as set out in this ES shall not apply to Single Practice PCNs and the obligations placed on the Practice through its PCN Grouping shall apply directly to the Practice.

6. Site designation and premises requirements

6.1. The Practice will have nominated and have access to the Designated Site as set out in its Tender Response Document.

- 6.2. The Vaccination Outreach Services and the administration of COVID-19 vaccinations may take place:
 - 6.2.1. [insert details of the communities, roving models etc that the Region is commissioning as per competition/prospectus].
- 6.3. Any amendments, additions or the removal of the Designated Site and/or any of the communities set out in paragraph 6.2 shall only be permitted with the agreement (in writing) 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 and any premises from which the Practice provides the Vaccination Outreach Services and/or the administration of the vaccinations to undertake an assessment of the readiness of those premises and the Practices within the PCN Grouping to deliver the services as set out in this arrangement or to ensure that the services are being delivered in accordance with this arrangement. The Commissioner may authorise other organisations to act on its behalf in undertaking such an assessment visit. The Practices will be notified by the Commissioner in advance of any visit and the details of who will undertake that visit.
- 6.5. COVID-19 vaccinations may only be offered to Patients in accordance with paragraph 7.
- 6.6. The PCN Grouping must ensure that appropriate measures are taken to ensure the integrity of the cold chain as well as meeting all other relevant standards throughout the Term.
- 6.7. Where vaccinations are administered to those under the age of 18 years the Practice must ensure that the relevant vaccinator has a Disclosure and Barring Service (DBS) certificate.
- 6.8. The Practice 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.
- 6.9. The Practice 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.

6.10. The Practice must inform the Commissioner immediately if, for any reason, a Designated Site or any premises from which the Practice provides the Vaccination Outreach Services and/or the administration of the vaccinations ceases to meet the criteria set out in this ES.

7. Patient eligibility

- 7.1. The Vaccination Outreach Services shall be provided in accordance with paragraph 6.2 and shall include but are not limited to:
 - 7.1.1. education and sharing resources with individuals;
 - 7.1.2. providing details on the COVID-19 vaccination and the benefits of receiving the vaccination;
 - 7.1.3. providing details on other vaccinations for which the Patient is eligible and the benefits of those vaccinations;
 - 7.1.4. signposting to other appropriate NHS services; and
 - 7.1.5. commitments set out in the Tender Response Document which is incorporated by reference as if it were annexed to this ES and are requirements as to the deivery of the Vaccination Outreach Services.
- 7.2. The Practice 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 general practice and where the following conditions are met and the administration of vaccinations:
 - 7.2.1. are provided in accordance with the Tender Response Document which is incorporated by reference as if it were annexed to this ES and are requirements as to the deivery of the administration of the vaccination;
 - 7.2.2. are provided proactively by seeking Patients in the community in accordance with paragraph 6.2;
 - 7.2.3. service aim is to reduce health inequalities by reaching underserved individuals and/or communities and inclusion groups;

- 7.2.4. does not include vaccination of Patients resident in care homes and/or housebound patients.
- 7.3. The Commissioner will announce the authorisation of JCVI Cohorts for vaccination by Practices.
- 7.4. The Practice must make arrangements and, subject only to Patient choice must administer the COVID-19 vaccination to specified JCVI Cohorts or specified groups of Patients within a JCVI Cohort.

8. Service description

- 8.1. The Practice must provide the Vaccination Outreach Services and the administration of the vaccinations in accordance with paragraphs 6.2 and 7 and must:
 - 8.1.1. ensure that vaccination is provided in line with the Green Book, including relevant details on the treatment of anaphylaxis and secure storage and disposal of clinical waste. The Practice must ensure that it has a process in place to check any updates to the Green Book;
 - 8.1.2. offer co-administration of the COVID-19 and seasonal influenza vaccinations to each Patient the Practice is able to vaccinate in accordance with this ES (and the Seasonal Influenza ES) and shall only administer vaccinations to Patients who meet the requirements set out in the Green Book;
 - 8.1.3. only administer vaccinations during the Term of this ES;
 - 8.1.4. 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; and
 - 8.1.5. ensure that, where the vaccine 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 Practice should encourage the Patient to make or attend a follow up appointment to receive any subsequent dose(s).
- 8.2. The Practice must follow all current guidance published by the JCVI, the Commissioner, MHRA and/or UKHSA on:

- 8.2.1. which vaccine is the most suitable for each Patient;
- 8.2.2. handling and manipulation of the vaccine;
- 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 JCVI, the Commissioner, MHRA 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 UKHSA². 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.
- 8.5. The Practice must ensure that it has in place suitable arrangements to prevent the disruption of other services or obligations of the Practice under its primary medical services contract.
- 8.6. The Practice should advise the Patient 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 eligible Patients to other vaccinations, as appropriate.

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² <u>https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-vaccination</u>

9. Patient access and service availability

- 9.1. The Practice must ensure that the delivery of the vaccination services are accessible, appropriate and sensitive to the needs of all Patients. No Patient shall be excluded or experience particular difficulty in accessing and effectively accessing vaccination services due their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age. Patients do not require an NHS number and should not be denied COVID-19 vaccination on this basis.
- 9.2. PCN Groupings are encouraged to sign up to use the NBS for COVID-19 vaccinations and comply with the conditions of sign up. Seasonal influenza vaccinations including co-administered COVID-19 and seasonal influenza vaccinations appointments must not be posted to the NBS unless notified by the Commissioner. This should not prevent Patients being offered each of the vaccinations where clinically appropriate and in accordance with paragraph 8.1.2.
- 9.3. Patients who have booked appointments with the NBS may ordinarily have eligibility confirmed prior to booking. The Practice must confirm each Patient's eligibility prior to administration of the vaccination.
- 9.4. The Practice must ensure that any Patient whose appointments are not made through the NBS are eligible for a vaccination as set out in this ES and that arrangements are made for administration of any subsequent dose(s) of a multi-dose regimen where appropriate.
- 9.5. The Practice must deliver the Vaccination Outreach Services through flexible community led delivery models to improve uptake and engagement with communities as more particularly set out in their Tender Response Document. 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 Practice, in collaboration with other Practices in the PCN Grouping, will be required to operate the Vaccination Outreach Services and clinics for the administration of the vaccinations to meet the needs of the local population as agreed by the Commissioner. Actual delivery hours shall be agreed with the Commissioner taking into account JCVI guidance on dosing intervals, the size of the local population eligible for vaccination and available vaccine supply, as well as the need to tailor service delivery to

meet the needs of the communities set out in the Tender Response Document.

- 9.7. The Commissioner recognises that outreach services are necessarily designed to be highly accessible for particular communities and therefore 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 Practice is able to demonstrate that the equivalent extended hours are provided at an alternative time for the convenience of patient access.
- 9.8. In the event that the Practice needs to temporarily suspend the administration of vaccinations by the PCN Grouping in accordance with this ES, this shall be agreed with the Commissioner and relevant changes must be made as soon as practicably possible to the NBS or relevant booking system.

10. Assessment and consent

10.1. The Practice must:

- 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 (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) 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 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.

11. Training

- 11.1. All persons involved in the provision of this ES (whether delivering the Vaccination Outreach Services or by vaccinations directly or supervising others providing vaccination) must adhere to all relevant professional standards, regardless of the setting.
- 11.2. Vaccinations Outreach Services must be provided by appropriately trained and supervised staff.
- 11.3. Vaccinations must be administered by an appropriately trained member of staff authorised under appropriate clinical supervision and using an appropriate legal mechanism.
- 11.4. All persons involved in the preparation of 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.
- 11.5. The Practice 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 vaccinations must:
 - 11.5.1. have completed the additional online COVID-19 specific training modules available on the e-learning for healthcare website³;
 - 11.5.2. have the necessary experience, skills and training⁴, including training with regard to the recognition and initial treatment of anaphylaxis;
 - 11.5.3. refer to and 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

³ https://portal.e-lfh.org.uk/Component/Details/675208

⁴https://www.gov.uk/government/publications/covid-19-vaccinator-training-recommendations/training-recommendations-for-covid-19-vaccinators

- 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)⁵.
- 11.6. The Practice must be assured to administer all COVID-19 vaccine types as required by the Commissioner.
- 11.7. The Practice must ensure that it is familiar with all guidance relating to the administration, handling and storage of the different types of vaccine and that it takes steps to reduce risks associated with the handling of different vaccine types.
- 11.8. The Practice 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 ES.

12. Vaccine handling and storage

- 12.1. The Practice must ensure that all vaccines are received, stored, prepared and subsequently transported (where appropriate) in accordance with the relevant manufacturer's, the UKHSA's⁶ and the Commissioner's instructions and all associated guidance set out in the 'Storage distribution 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 ES must also be undertaken with appropriate cold chain management, clinical oversight and in accordance with governance arrangements in place for this ES.
- 12.2. The Practice must ensure that any refrigerator used to store vaccine has sufficient space to store different vaccine types, with separation to reduce the risk of selection errors, and sufficient airflow to maintain effective cooling. All refrigerators in which vaccines are stored must have a thermometer that records maximum and minimum temperatures appropriate to the vaccine being administered. Readings must be recorded from that thermometer on all working days and appropriate action taken when readings are outside the recommended temperature.

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

⁶ UKHSA (previously PHE's) ordering, storing and handling protocol

https://www.gov.uk/government/publications/protocol-for-ordering-storing-and-handling-vaccines

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 vaccination to the population.

12.4. COVID-19 vaccines:

- 12.4.1. are allocated to the PCN Grouping Designated Site, and the Practice must not share the vaccine with other providers unless it is expressly in accordance with its PCN Grouping COVID-19 Outreach ES Collaboration Agreement; and
- 12.4.2. will be supplied to the Designated Site. The PCN Grouping will be responsible for the supply of consumables as may be required (for example PPE and items related to Infection Prevention and Control). The Commissioner may supply needles and syringes and will notify the Practice where this is the case. The Practice must be available to accept vaccine deliveries at the Designated Site according to the delivery schedule provided by the Commissioner.

13. Monitoring, reporting and record keeping

- 13.1. The Practice 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 it receives the COVID-19 Vaccination Bulletin published by the Commissioner so key information in relation to the delivery of this ES can be communicated in a timely manner.
- 13.2. The Practice through its PCN Groupings must monitor and report all activity information in accordance with the monitoring and reporting standards as published by the Commissioner and in accordance with its primary medical services contract and relevant legislation. This includes guidance published by the Commissioner on the recording of COVID-19 vaccination appointments to ensure consistent national data captures and records maintained in accordance with paragraph 5.7.1.
- 13.3. The Practice 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 Practice must adhere to defined standards of record keeping as set out at paragraph 18(12) of the SFE ensuring that the vaccination event is recorded the same day that it is administered within an approved Point of Care System⁷.
- The administration of the vaccination to a Patient must be recorded in the 13.5. Point of Care system on the day of the administration of the vaccination and must be recorded with an 'Offsite outreach event' flag in the Point of Care system. Where the Point of Care System is unavailable due to exceptional circumstances beyond the control of the Practice 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 vaccination 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 Practice shall not be eligible for the item of service fees and any associated additional payments as set out at paragraph 14. Where the item of service fee and/or any additional payments are claimed and/or automatically submitted payments shall be recoverable by the Commissioner in accordance with paragraph 14.11.
- 13.6. Where a record of the vaccination needs to be amended or has not been created on the Point of Care system, the Practice is responsible for undertaking the amendment or creation as soon as reasonably possible following notification that the record contains an error.
- 13.7. The Practice operating within the PCN Grouping:
 - 13.7.1. must only enter new vaccinations into a single Point of Care System in any calendar month except:
 - 13.7.1.1. 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

⁷ Point of Care - NHS Digital

- 13.7.1.2. subject to paragraph 13.5, where it is necessary to include amendments to vaccination events previously recorded; and
- 13.7.2. is responsible for ensuring that the quality and connectivity of access to the Point of Care System is sufficient to ensure the timely recording of vaccinations and to support sufficient access to the Point of Care System in accordance with this paragraph 13.
- 13.8. The Practice 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.
- 13.9. The Practice is expected to follow the UKHSA: "Vaccine incident guidance" responding to errors in vaccine storage, handling and administration.
- 13.10. The Practice 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.⁹

14. Payment arrangements¹⁰

- 14.1. Subject to paragraph 14.3, from the Expected COVID-19 Vaccination Administration Commencement Date to 31 March 2026 and subject to compliance with this ES, the Commissioner will pay:
 - 14.1.1. an item of service payment of £7.54 to the Practice for administration of each COVID-19 vaccination to each Patient; and
 - 14.1.2. where the Commissioner notifies the Practice in advance (including the timeframe to which this £2.50 payment shall apply), the Commissioner will pay £2.50 to the Practice for the administration of each COVID-19 vaccination to each Patient

https://www.gov.uk/government/publications/records-management-code-of-practice-for-healthand-social-care

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https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-

¹⁰ For further information on payments please see the PCN Finance and Payments Guidance available here: https://future.nhs.uk/vaccsandscreening/view?objectID=38665872

where the seasonal influenza vaccination is not announced and authorised for vaccination by the Practice.

- 14.2. [From the Vaccination Outreach Services Commencement Date to 31 March 2026 and subject to compliance with this ES, the Commissioner will pay:
 - 14.2.1. [insert] to the Practice for the Vaccination Outreach Services.
- 14.3. The Commissioner will pay the sums as set out at paragraph 14.1 and 14.2 unless the Commissioner notifies the Practice of a change to the payment sums on at least 49 days' notice.
- 14.4. Claims for payments for this ES set out in paragraph 14.1 must be made via the Manage Your Service (MYS) portal provided by the NHS Business Services Authority (the NHSBSA). Claims should be made by the 5th day of the month following the month in which administration of the vaccination occurred (the "Expected Claim Date") but will be accepted by the NHSBSA if they are submitted within three months of the Expected Claim Date. Any claims that are submitted later than three months following the Expected Claim Date will not be processed and the Practice will not receive any item of service payment for those vaccinations.
- 14.5. Claims for payments for this ES set out in paragraph 14.2 shall be paid in accordance with the method agreed in writing with the Commissioner.
- 14.6. Claims for payments for this ES set out in paragraph 14.1 will only be paid where Vaccination Outreach Services have been provided and:
 - 14.6.1. the Patient in respect of whom payment is being claimed was within one of the eligible JCVI Cohorts and that JCVI Cohort was announced and authorised by the Commissioner for the administration of the vaccination by the Practice, at the time the vaccination was administered:
 - 14.6.2. the Practice has used a COVID-19 vaccine supplied and recommended in accordance with the latest advice:
 - 14.6.3. the administration of the vaccination has been recorded on the Point of Care System on the day of the administration of the vaccination to the Patient and has been recorded with an 'Offsite outreach event' flag in the Point of Care system. In exceptional circumstances, where it has not been possible to

record the vaccination event on the day of the administration of the vaccination, and the Practice has recorded the exceptional circumstances on the Point of Care system as soon as possible afterwards and within 15 days of the day on which the vaccination was administered, the Practice will be eligible for the item of service fees and any associated additional payments. Where the record of the vaccination event is not created within 15 days of the vaccination being administered, the Practice shall not be eligible for the item of service fees and any associated additional payments;

- 14.6.4. the 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 relating to the delivery of the COVID-19 vaccination programme and/or under its COVID-19 Outreach ES Vaccination Collaboration Agreement) in respect of the vaccine or vaccination event;
- 14.6.5. the claim for payment was submitted in accordance with paragraph 14.4; and
- 14.6.6. the Patient's vaccinations have been administered by the Practice's PCN Grouping.
- 14.7. Collaborating Practices must make arrangements within its PCN Grouping for the nomination of a host Practice for the PCN Grouping which will receive payments due under this ES for and on behalf of the Practice. This is necessary as existing systems are unable to support payment in a timely manner to individual Practices and to facilitate the payment system 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 Practice. The host Practice will then receive data which on the administration of vaccinations. 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 providing no less than 10 days' notice of the change and cannot be made retrospectively. Single Practice PCNs will receive vaccination payments directly.

- 14.8. If the Practice does not satisfy all relevant provisions of this ES, the Commissioner may determine to withhold payment of all or any part of, an amount due under this ES that is otherwise payable.
- 14.9. The Practice must comply with any reasonable requests to facilitate post payment verification. This may include auditing claims to ensure that it meets the requirements of this ES.
- 14.10. Payment under this ES, or any part thereof, is conditional on the Practice satisfying the following:
 - 14.10.1. entering into this ES, including any variations and updates;
 - 14.10.2. subject to paragraph 5.11, having in place a COVID-19
 Outreach ES Vaccination Collaboration Agreement that
 complies with the requirements of paragraph 5.7;
 - 14.10.3. complying (and maintaining compliance) with the requirements of this ES;
 - 14.10.4. making available to the Commissioner any information under this ES which the Commissioner needs and the Practice either has or could be reasonably expected to obtain;
 - 14.10.5. making any returns (including payment claims as required by this paragraph 14) or providing any information reasonably required by the Commissioner (or on the Commissioner's behalf) (whether computerised or otherwise) to support payment and do so promptly and fully; and
 - 14.10.6. ensuring that all information supplied pursuant to or in accordance with this paragraph 14 is accurate.
- 14.11. The Practice may not claim payment for Patients vaccinated outside of the PCN Grouping (for example, at a vaccination centre, operated by another provider).
- 14.12. If the Commissioner makes a payment to a Practice under this ES and:
 - 14.12.1. the 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);

- 14.12.2. the Commissioner was entitled to withhold all or part of the payment because of a breach of a condition attached to the payment, but is unable to do so because the money has already been paid; or
- 14.12.3. the Commissioner is entitled to repayment of all or part of the money paid,

the Practice agrees that the Commissioner may recover the money paid by deducting an equivalent amount from any payment payable to the 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 that equivalent amount.

14.13. Where the Commissioner is entitled under this ES to withhold all or part of a payment because of a breach of a payment condition, and the Commissioner 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 Practice the amount withheld or recovered, if the breach is cured.

15. Variations to and subsequent withdrawal from this ES

- 15.1. 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. The Practice will also be notified of any changes by the Commissioner.
- 15.2. In order to simplify the process, where there are any variations to this ES after the Practice's submission of its Tender Response Document, the Practice which has confirmed its agreement to enter into this ES will be deemed to agree to the variations, unless the Practice notifies the Commissioner in accordance with paragraph 15.3.
- 15.3. If the Practice cannot meet the revised requirements of this ES it must withdraw from this ES by serving written notice on the Commissioner to that effect with supporting reasons as to why it cannot meet the revised requirements, such notice must be received by the Commissioner no later

- than 42 days after publication of the relevant variation and providing no less than 42 days' written notice of the Practice's withdrawal. A collaborating Practice will also need to make the necessary amendments to the COVID-19 Outreach ES Vaccination Collaboration Agreement.
- 15.4. Following notice of its intention to withdraw from the ES, but prior to the actual withdrawal date, a collaborating Practice must comply with its COVID-19 Outreach ES Vaccination Collaboration Agreement and cooperate with its PCN Grouping during and following its withdrawal from this ES.

16. Sub-contracting arrangements

- 16.1. The Commissioner acknowledges that to deliver the services pursuant to this ES, the collaborating Practice may require the ability to sub-contract the delivery of the required clinical services to another collaborating Practice in the PCN Grouping or another party. Where a Practice is considering sub-contracting arrangements related to the provision of services under the ES, the 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.
- 16.2. The collaborating Practice and its PCN Grouping must make available, on request from the Commissioner, any reasonable information relating to the sub-contracting arrangements and reporting information relating to the delivery of this ES.
- 16.3. Insofar as the sub-contracting of the clinical services pursuant to this ES is necessary to deliver these services within a PCN Grouping and is compliant with the primary medical services legal and contractual requirements, the Commissioner will not object to the sub-contracting.