Classification: Official



General Practice Enhanced Service Specification COVID-19 vaccination programme: 1 September 2024 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 Response Document and has been awarded this arrangement to provide services 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 has been developed from earlier phases of the COVID-19 vaccination programme. It is a national specification that cannot be varied locally.
- 1.3. This 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.
- 1.4. An aim of this ES is to maximise the uptake and co-administration of COVID-19 and seasonal influenza vaccinations where possible and to ensure that vaccination services are provided from a variety of settings and effectively utilise available staff from across primary care.
- 1.5. 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 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 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, Practices may update their COVID-19 ES Vaccination Collaboration Agreement to include the delivery of services under this ES.
- 1.6. 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 or guidance. This should include signposting to other vaccinations where, if eligible, the Patient indicates that

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.

- 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).
- 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.
- 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. "Care Home" means specific types of care homes which shall be announced and authorised by the Commissioner;
 - 2.2.2. "Commencement Date" means 1 September 2024 where the Provider submitted a Response Document on or before 23:59 on 27 June 2024 or the date notified by the Commissioner where the Provider submitted a Response Document after 23:59 on 27 June 2024;
 - 2.2.3. "Commissioner (NHSE)" means NHS England;
 - 2.2.4. "COVID-19 ES Vaccination Collaboration Agreement" means the agreement entered into by 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 5.7;
 - 2.2.5. "CQC" means the Care Quality Commission;

- 2.2.6. "Designated Site" means the premises nominated by the PCN Grouping and approved by the Commissioner 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;
- 2.2.7. "Designation Process" means the COVID-19 Assurance and Site Designation process set out in the COVID-19 Vaccination Site Signup Process Guidance which is undertaken to ensure that the Designated Site meets the specified site criteria and which may be updated and amended as required from time to time and is an integral part of this ES;
- 2.2.8. "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;
- 2.2.9. "Expected Service Commencement Date" means the date from which the administration of COVID-19 vaccinations shall commence and which shall be following an announcement by the Commissioner. Where the date announced by the Commissioner is no less than 4 weeks following the Commencement Date, the administration of vaccinations shall commence from the date announced by the Commissioner. Where the date announced by the Commencement Date, the administration of vaccinations shall commence on a date to be agreed with the Commissioner. Where the Commencement Date is later than the date announced by the Commissioner the administration of vaccinations shall commence from the Commencement Date;
- 2.2.10. **"GPhC"** means the General Pharmaceutical Council:
- 2.2.11. "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;

- 2.2.12. "**JCVI**" means the Joint Committee on Vaccination and Immunisation;
- "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 as set out at paragraph 3.6;
- 2.2.19. "PCN Grouping" means the group of Practices which together submitted a Response Document and collaborate to deliver the services in accordance with this ES, which may include established Primary Care Networks, and additional neighbouring Practices and/or other groups of Practices working together. They must do so under a COVID-19 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 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. "Response Document" means the response to the COVID-19 Vaccination Site Signup Process Guidance whereby the Practice is awarded this arrangement to deliver services under this ES;
- 2.2.25. "Seasonal Influenza ES" means each of the Seasonal Influenza Vaccination Programme Enhanced Service Specifications for 2024/25 and 2025/26 which are capable of being entered into by the Practice during the Term;
- 2.2.26. "**SFE**" means the NHS General Medical Services Statement of Financial Entitlements Directions 2024;
- 2.2.27. "Short Term/Temporary Site" means a clinically appropriate short-term or temporary clinic run by the Practice through its PCN Grouping to administer vaccinations (for example, a one-off clinic, a clinic running for a week, a clinic running twice a week for two weeks). This may be at or away from the Designated Site. The vaccine may only be stored overnight at CQC/GPhC registered premises, in accordance with approved medicines management arrangements and the Practice will use vaccine and any related consumables and systems supplied to the Designated Site;
- 2.2.28. "Site Capacity" means at least 100 COVID-19 vaccinations per week which the Practice has offered to provide (and which will not otherwise impact its delivery of primary medical services) through its PCN Grouping, in its Response Document and has been agreed by the Commissioner to be administered during each week of the Term, subject to Patient demand;
- 2.2.29. "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 with COVID-19 vaccine. It is a system change in line with JCVI Guidance to ensure the defined population in England is offered and has access to a COVID-19 vaccination;

- 2.2.30. "Term" means the period from the Expected Service Commencement Date to the End Date; and
- 2.2.31. "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 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, extend the Term by up to 12 months.
- 3.3. The administration of vaccinations shall commence with effect from the Expected Service Commencement Date.
- 3.4. Where the Practice, together with the other Practices in the PCN Grouping, is unable to commence the administration of vaccinations within 4 weeks of the Expected Service Commencement Date, the Practice must notify the Commissioner as soon as reasonably possible.
- 3.5. The Commissioner may agree with the Practice, together with the other Practices in the PCN Grouping, an extension not exceeding 8 weeks following the Expected Service Commencement Date to commence the administration of vaccinations. Failure to begin the administration of vaccinations within the agreed timeframe will result in termination of the ES on a date to be notified by the Commissioner to the Practice.
- 3.6. Where there is (in the reasonable view of the Commissioner) significantly reduced Patient demand for the administration of COVID-19 vaccinations, there is unacceptable wastage of the COVID-19 vaccine and/or the Designated Site does not represent acceptable value for money to the Commissioner, the Commissioner may require the Practice together with the other Practices in the PCN Grouping to suspend the COVID-19 vaccination services (a "Pause").

- 3.7. 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 and/or the Designated Site represents acceptable value for money to the Commissioner and the Commissioner shall, acting reasonably, reconsider whether it remains appropriate to continue with the Pause.
- 3.8. During a Pause, the Practice shall not administer COVID-19 vaccinations and shall not be entitled to claim or receive any payment for the administration of COVID-19 vaccinations except in respect of the services which took place prior to the date on which the Pause occurred unless in the case of unavoidable and limited costs which have been exceptionally agreed with the Commissioner in advance of such costs being incurred.
- 3.9. While the services are Paused the Commissioner and the Practice shall use all reasonable efforts to ensure that no further Patients are referred to the Practices within the PCN Grouping for vaccination and should direct Patients to available services, as appropriate.
- 3.10. Where there is, in the reasonable view of the Commissioner a requirement to increase capacity at pace (Surge), Practices shall agree with the Commissioner their role in the system wide response to the Surge, both in terms of increased volume and rapid timeframe for the administration of COVID-19 vaccinations.
- 3.11. It is a condition of this ES that the Practice must also deliver each Seasonal Influenza ES during the Term. The offer of co-administration of the COVID-19 and seasonal influenza vaccinations, subject to vaccine availability, must be made to each 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 comes to an end (and which shall be announced by the Commissioner);
 - 3.12.2. automatically where the Practice has not provided vaccinations under the Seasonal Infleunza ES for the preceding 56 days or otherwise agreed by the Commissioner and save for in exceptional

- circumstances where the seasonal influenza vaccination programme has come to an end before the COVID-19 vaccination programme;
- 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 or on such notice as the Commissioner deems appropriate where the Practice is unable to meet the Site Capacity;
- 3.12.7. immediately where the Practice does not commence the administration of vaccinations in accordance with paragraph 3.3 to 3.5; or
- 3.12.8. automatically on the same date as the termination of the Practice's primary medical services contract.
- 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, the Practice shall work with the Commissioner and any providers commissioned by the Commissioner for the delivery of any subsequent doses of COVID-19 vaccination to Patients.

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 through the PCN Grouping will have the ability to administer the Site Capacity (subject to the vaccine supply). 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 and support the high uptake of vaccinations.
- 4.7. The Practice, together with the other 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 ES Vaccination Collaboration Agreement.

5. Collaboration requirements and PCN Groupings

- 5.1. 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 vaccinations at scale and 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 Response Document) a Designated Site for delivering COVID-19 vaccinations under this ES.
- 5.7. The Practice must have in place a COVID-19 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 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;
- 5.7.2. 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;
- 5.7.3. appropriate arrangements for communicating with Patients, including but not limited to call/re-call as required by this ES;
- 5.7.4. 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;
- 5.7.5. financial arrangements between the collaborating 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];
- 5.7.6. arrangements in relation to use of the Designated Site and any other relevant premises (as required);
- 5.7.7. sub-contracting arrangements (as required);
- 5.7.8. a lead contact email address for the PCN Grouping which shall be supplied to the Commissioner for use in disseminating information urgently;
- 5.7.9. 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;

- 5.7.10. appropriate arrangements to ensure that the Practice can identify, if appropriate, which Patients receive vaccinations under this ES; and
- 5.7.11. 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 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.
- 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 delivery arrangements in line with COVID-19 stock forecasting and ordering arrangements including:
 - 5.10.1. planning clinics 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.

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 Response Document, from which COVID-19 vaccinations must be administered unless otherwise set out in the ES and/or there is a specific reason not to, including:
 - 6.1.1. in the reasonable opinion of the Practice, attendance of the Patient is required and it would be inappropriate for the Patient to attend at the Designated Site, the Practice must provide the vaccination to the Patient at another location and the Practice must make all reasonable efforts to ensure the Patient is vaccinated; and
 - 6.1.2. where the Practice makes arrangements to vaccinate Patients resident in care homes at their care home of residence.
- 6.2. Any amendments, additions or the removal of the Designated Site shall only be permitted with the agreement of the Commissioner.
- 6.3. From the Commencement Date to the End Date, the Commissioner shall be entitled to access and inspect the Designated Site to undertake an assessment of the readiness of the Designated Site 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.

- 6.4. Vaccinations may be administered at locations other than the Designated Site where:
 - 6.4.1. required by the Commissioner in accordance with paragraph 7; or
 - 6.4.2. the Practice, through its PCN Grouping, notifies the Commissioner (by reasonable notice and in advance) that it intends to deliver a Short Term/Temporary Site for the administration of vaccinations and to improve vaccination uptake on given date(s) and/or time(s) to permit vaccination of specific Patient groups).
- 6.5. Where vaccinations are administered at a location other than the Designated Site, 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.
- 6.6. Where vaccinations are administered to those under the age of 18 years and/or undertaken in the Patient's own home (including a care home), the Practice must ensure that the relevant vaccinator has a Disclosure and Barring Service (DBS) certificate.
- 6.7. 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.
- 6.8. 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.
- 6.9. The Practice must inform the Commissioner immediately if, for any reason, a Designated Site ceases to meet the criteria set out in this ES.

7. Patient eligibility

- 7.1. 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.
- 7.2. The Commissioner will announce the authorisation of JCVI Cohorts for vaccination by Practices.

- 7.3. The Practice must make arrangements and, subject only to Patient choice or paragraph 7.5, must administer the COVID-19 vaccination to specified JCVI Cohorts or specified groups of Patients within a JCVI Cohort. Subject to JCVI guidance, the Commissioner expects these Patients to include:
 - 7.3.1. eligible patients resident in a Care Home or who are staff working in a Care Home within:
 - 7.3.1.1. 8 weeks of the Commissioner's announcement to commence Care Home COVID-19 vaccinations for the relevant COVID-19 vaccination campaign provided that the 8 weeks shall not begin on a date earlier than the Expected Service Commencement Date, set out at paragraph 3.3; or
 - 7.3.1.2. as soon as reasonably possible;
 - 7.3.2. severely immunosupressed patients as defined in the Green Book;
 - 7.3.3. housebound patients; and
 - 7.3.4. Children aged 6 months to 4 years in a clinical risk group (as defined in the Green Book) where requested by the Commissioner to vaccinate Patients in this cohort following a JCVI announcement, announcement and authorisation by the Commissioner and subject to clinical guidelines on the interval between doses.
- 7.4. The Practice must administer the vaccinations to Patients in the priority order announced and authorised by the Commissioner.
- 7.5. In exceptional circumstances only, the Commissioner and the Practice may agree in writing, that the Practice shall not be required to comply with the administration of vaccinations to certain Commissioner mandated JCVI Cohorts of Patients or specified groups of Patients.
- 7.6. The Practice may only administer the COVID-19 vaccination to those Patients who are included in a JCVI cohort announced and authorised by the Commissioner where the Patient also fulfils one of the following criteria:
 - 7.6.1. whose name is included on the Practice's list of registered patients;
 - is an unregistered patient (including those without an NHS number);
 or

7.6.3. is 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 but has chosen to receive their vaccination from the PCN Grouping.

8. Service description

- 8.1. The Practice must liaise with its own PCN and where appropriate other PCNs 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.
- 8.2. To support a high uptake of vaccinations and minimise wastage, the Practice:
 - 8.2.1. must undertake a call/re-call service, write, text or call Patients (as appropriate) for all non-age-based cohorts; and
 - 8.2.2. is strongly encouraged to undertake a call/re-call service, write, text or call Patients (as appropriate) for all age-based cohorts.

8.3. The Practice must:

- 8.3.1. actively co-operate with any national call/re-call service requirements including where Practices are not being requested to administer vaccinations to Patients during a Pause;
- 8.3.2. maintain clear records of how it has contacted (including 'called' and recalled) Patients as identified by paragraph 8.2;
- 8.3.3. ensure that vaccinations are provided in line with the Green Book, including relevant details on the treatment of anaphylaxis and secure storage and disposal of clinical waste. The Practice must ensure that it has a process in place to check any updates to the Green Book;
- 8.3.4. 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;

- 8.3.5. only administer vaccinations during the Term of this ES;
- 8.3.6. 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;
- 8.3.7. identify people eligible for COVID-19 vaccination who present at the general practice and encourage them to be vaccinated; and
- 8.3.8. 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).
- 8.4. The Practice must follow all current guidance published by the JCVI, the Commissioner, MHRA and/or UKHSA on:
 - 8.4.1. which vaccine is the most suitable for each Patient;
 - 8.4.2. handling and manipulation of the vaccine;
 - 8.4.3. the intervals between doses where multiple doses are required;
 - 8.4.4. the number of doses of each vaccine required to achieve the desired immune response; and
 - 8.4.5. any other relevant guidance relating to the administration of the different types of vaccine and the different JCVI Cohorts from time to time.
- 8.5. 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.
- 8.6. 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

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 $^{^2 \, \}underline{\text{https://www.gov.uk/government/publications/covid-19-vaccination-what-to-expect-after-} \underline{\text{vaccination}}$

- 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.
- 8.7. 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.
- 8.8. The Practice should advise the Patient attending at the Designated Site 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 eligible Patients to other vaccinations, as appropriate.

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 8.3.4
- 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 is strongly encouraged to offer vaccinations through advertised walk-in clinics or alternative arrangements to improve uptake or engagement with communities as agreed with the Commissioner. Processes must be put into place to support Patients with communication needs and/or encourage vaccination of Patients who experience other difficulties in accessing healthcare.
- 9.6. The Practice, in collaboration with other 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. Actual delivery hours shall be agreed with the Commissioner having regard to the Site Capacity, JCVI guidance on dosing intervals, the size of the local population eligible for vaccination and available vaccine supply.
- 9.7. The Commissioner 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 (including checklists relevant to the vaccination of those under 18 years of age).

11. Training

- 11.1. All persons involved in the provision of this ES (whether delivering vaccinations directly or supervising others providing vaccinations) must adhere to all relevant professional standards, regardless of the setting.
- 11.2. Vaccinations must be administered by an appropriately trained member of staff authorised under appropriate clinical supervision or an appropriate legal mechanism.
- 11.3. 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.
- 11.4. 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:
 - 11.4.1. have completed the additional online COVID-19 specific training modules available on the e-learning for healthcare website³;

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

- 11.4.2. have the necessary experience, skills and training⁴, including training with regard to the recognition and initial treatment of anaphylaxis;
- 11.4.3. 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
- 11.4.4. 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.
- 11.5. The Practice must be assured to administer all COVID-19 vaccine types as required by the Commissioner.
- 11.6. 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.
- 11.7. 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.

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

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

- 12.2. 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.
- 12.3. Appropriate procedures must be in place to ensure stock rotation, monitoring of expiry dates and appropriate use of multi-dose vials to ensure that wastage is minimised and stock holdings of vaccine remain low to support the maximisation of vaccinations to the population.

12.4. COVID-19 vaccines:

- 12.4.1. are allocated to the 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 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.
- 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. 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 vaccinations being added to the Point of Care System on a different day than the vaccinations were administered. Where the record of the vaccination event is not created within 15 days of the vaccination being administered, the 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:

⁷ Point of Care - NHS Digital

- 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
 - 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 internet broadband at the Designated Site is sufficient to support access to the Point of Care System during the hours of operation or as agreed with the Commissioner.
- 13.8. 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: "<u>Vaccine incident guidance</u>", 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.⁸

14. Payment arrangements9

- 14.1. From the Expected Service Commencement Date to 31 March 2025 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;
 - 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

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⁸ https://www.gov.uk/government/publications/records-management-code-of-practice-for-health-and-social-care

⁹ For further information on payments please see the PCN Finance and Payments Guidance available here: https://future.nhs.uk/CovidVaccinations/view?objectID=38665872

of each COVID-19 vaccination to each Patient where the seasonal influenza vaccination is not announced and authorised for vaccination by the Practice; and

- 14.1.3. £10.00 to the Practice for administration of each COVID-19 vaccination to each Patient where:
 - 14.1.3.1. the medical condition of a Patient is such that, in the reasonable opinion of the 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:
 - 14.1.3.2. that Patient requires administration of a vaccination;
 - 14.1.3.3. the Practice has recorded the status of the Patient in the Point of Care System prior to making the claim for payment; and
 - 14.1.3.4. that Patient has been offered co-administration of a seasonal influenzas vaccination where the Patient is eligible for a seasonal influenza vaccination; and

which for the avoidance of doubt, excludes Patients resident in Care Homes.

- 14.2. From 1 April 2025 and subject to continued compliance with this ES the Commissioner will pay the sums as set out at paragraph 14.1 unless the Commissioner notifies the Practice of a change to the payment sums from 1 April 2025 at least 49 days prior to 1 April 2025.
- 14.3. Claims for payments for this ES set out in paragraph 14.1 and 14.2 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.
- 14.4. Claims submitted in accordance with this ES will only be paid where:

- 14.4.1. 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;
- 14.4.2. the Practice has used a COVID-19 vaccine supplied and recommended in accordance with the latest advice;
- 14.4.3. 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. 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;
- 14.4.4. 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 ES Vaccination Collaboration Agreement) in respect of the vaccine or vaccination;
- 14.4.5. the claim for payment was submitted in accordance with paragraph 14.3; and
- 14.4.6. the Patient's vaccinations have been administered by the Practice's PCN Grouping.
- 14.5. The Practice must nominate a single Practice within the PCN Grouping to claim and receive (on its own behalf) COVID-19 vaccination payment for 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.

- 14.6. The Practice must make arrangements within its PCN Grouping for the nomination of a host Practice for the PCN Grouping which will receive vaccination 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 enables it to identify how many Patients on the Practice's list of registered patients have been vaccinated, for verification and the transfer of funds to the 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 providing no less than 10 days' notice of the change and cannot be made retrospectively.
- 14.7. 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.
- 14.8. 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.
- 14.9. Payment under this ES, or any part thereof, is conditional on the Practice satisfying the following:
 - 14.9.1. entering into this ES, including any variations and updates;
 - 14.9.2. having in place a COVID-19 ES Vaccination Collaboration Agreement that complies with the requirements of paragraph 5.7;
 - 14.9.3. complying (and maintaining compliance) with the requirements of this ES;
 - 14.9.4. 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;
 - 14.9.5. 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

- 14.9.6. ensuring that all information supplied pursuant to or in accordance with this paragraph 14 is accurate.
- 14.10. The Practice may not claim payment for Patients vaccinated outside of the PCN Grouping (for example, at a vaccination centre, operated by another provider).
- 14.11. If the Commissioner makes a payment to a Practice under this ES and:
 - 14.11.1. 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);
 - 14.11.2. 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
 - 14.11.3. 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.

14.12. 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. 14.13. The Commissioner may, at its discretion for example, in the event of a Surge, make additional payments to the Practice to support the administration of vaccinations in exceptional circumstances.

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 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. The Practice will also need to make the necessary amendments to the COVID-19 ES Vaccination Collaboration Agreement.
- 15.4. Following notice of its intention to withdraw from the ES, but prior to the actual withdrawal date, the Practice must comply with its COVID-19 ES Vaccination Collaboration Agreement and co-operate 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 Practice may require the ability to sub-contract the delivery of the required clinical services to another 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 Practice and its PCN Grouping must make available, on request from the Commissioner, any reasonable information relating to the subcontracting 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.