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Enhanced service specification Childhood influenza vaccination programme 2022/23

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1. Introduction

- 1.1 The enhanced Service Specification (ES) childhood seasonal influenza vaccination programme 2022/23 has been agreed between NHS England and the British Medical Association (BMA) General Practitioners Committee (GPC) in England.] It is a national specification that cannot be varied locally. Where it is necessary to amend it in line with recommendations or decisions of the Joint Committee on Vaccinations and Immunisations (JCVI), Medicines and Healthcare products Regulatory Agency (MHRA), vaccine manufacturers or Ministers, NHS England will discuss the required changes with the GPC. Therefore, the ES may be subject to amendments from time to time.
- 1.2 This ES is offered by the Commissioner (NHS England) to all general medical services, personal medical services and alternative provider medical services contract holders.
- 1.3 An ES is designed to cover enhanced aspects of clinical care, all of which are beyond the scope of essential and additional services. No part of this ES specification by commission, omission or implication defines or redefines essential or additional services.
- 1.4 All practices are offered the opportunity to sign up to this ES provided they meet the requirements of this specification. Where a practice agrees to participate in this ES, they will be expected to offer childhood seasonal influenza vaccinations to patients aged two and three years (but not aged four years). The arrangements to deliver this ES supersede any previous agreement. A 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.
- 1.5 The aim of this ES is to protect those children who are two and three years of age but not aged four on 31 August 2022 providing individual protection to those children, by offering protection against the most prevalent strains of the influenza virus. It is also to reduce the transmission of influenza in the wider population, some of whom are most at risk of serious illness or death should they develop influenza.

2. Commonly Used Terms

- 2.1 This specification is referred to as this 'ES'.
- 2.2 In this ES:
 - 2.2.1 'Adult ES' means the Enhanced Service Specification Seasonal influenza vaccination Programme 2022/23.
 - 2.2.2 The 'Commissioner (NHS England)' refers to the organisation with responsibility for contract managing these ES arrangements and this is NHS England.
 - 2.2.3 'Flu letter' means the annual flu letter available at the following website as updated from time to time <u>https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan/national-flu-immunisation-programme-2022-to-2023-letter</u>.
 - 2.2.4 'Green Book' means the green book available at the following website as updated from time to time <u>https://www.gov.uk/government/publications/influenza-the-greenbook-chapter-19</u>.
 - 2.2.5 'Influenza collaboration' means the group of practices which collaborate to deliver the services under this ES and where relevant under the Adult ES, which may include established Primary Care Networks, and additional neighbouring GP practices and/or other groups of GP practices working together. They must do so under an influenza ES vaccination collaboration agreement.
 - 2.2.6 'Influenza ES vaccination collaboration agreement' means the agreement entered into by GP practices, including those that are members of an established primary care network (PCN), and which incorporates the provisions that are required to be included in an influenza ES vaccination collaboration agreement in accordance with paragraph 5.
 - 2.2.7 'JCVI' means the Joint Committee on Vaccination and Immunisation.

- 2.2.8 'MHRA' means the Medicines and Healthcare products Regulatory Agency.
- 2.2.9 'Ministerial Decision' means a decision issued by the Secretary of State for Health and Social Care.
- 2.2.10 'Patient' means those patients eligible to receive the influenza vaccination in general practice as set out at paragraph 7.2.
- 2.2.11 'Practice' refers to a provider of essential primary medical services to a registered list of patients under a general medical services contract, personal medical services agreement or alternative provider medical services contract who has agreed with the Commissioner (NHS England) to deliver this ES.
- 2.2.12 'UKHSA' refers to 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 refence to its applicable successor from time to time.

3. Background and duration

- 3.1 This ES is for the Commissioner (NHS England) to commission the provision of seasonal influenza vaccinations to all children aged 2 and 3 years of age but not aged four years on 31 August 2022. This ES begins on 1 September 2022 and shall continue until 31 March 2023 unless it is terminated in accordance with paragraph 3.2.
- 3.2 This ES may be terminated on any of the following events:
 - 3.2.1 automatically when the childhood seasonal influenza vaccination programme comes to an end
 - 3.2.2 by the Commissioner (NHS England) providing not less than 28 days' notice to the practice
 - 3.2.3 where this ES is amended, by the practice providing not less than 28 days' notice to the Commissioner (NHS England), unless otherwise agreed with the Commissioner (NHS England).
- 3.3 The patients eligible for influenza vaccination under this ES are set out in paragraph 7.2. Vaccinations must only be administered to patients.
- 3.4 This ES may be updated from time to time as the vaccination programme develops and is subject to ministerial decision. This may include amendments to eligible cohorts and prioritisation of cohorts of patients and ongoing adaptation of the requirements within this ES.

4. Sign up process

- 4.1 Practices must indicate their willingness to participate in this ES before 31 August 2022, 23:59 unless otherwise agreed with the Commissioner (NHS England).
- 4.2 Where the medical condition of a patient is such that, in the reasonable opinion of the practice, attendance on the patient is required and it would be inappropriate for the patient to attend at the practice premises, the practice must provide the influenza vaccination to the patient at another location and the practice must make all reasonable efforts to ensure the patient is vaccinated.
- 4.3 The Commissioner (NHS England) may be able to support practices to work with community partners and other local providers as appropriate to identify pragmatic local solutions to vaccinating these patients at other locations.
- 4.4 Payment and activity recording will be managed using the Calculating Quality Reporting Service (CQRS)¹ and all practices must sign-up to CQRS by no later than 31 August 2022, 23:59. Payment under this ES is conditional on practices:
 - 4.4.1 entering into this ES, including any variations and updates
 - 4.4.2 complying with the requirements of this ES
 - 4.4.3 completing the influenza vaccination or course of influenza vaccinations (where multiple doses are required) to patients (unless exceptional circumstances apply).
- 4.5 A practice's participation in this ES shall only continue for so long as it is in compliance with its terms.

¹ Further guidance relating to CQRS and GPES will be provided by NHS Digital and the CSU Collaborative when services are updated.

5. Collaboration requirements/general

- 5.1 Practices may under the terms of this ES and where relevant the Adult ES collaborate to deliver influenza vaccinations to their patients in accordance with this paragraph 5 and Annex B, as part of an influenza collaboration. All practices which choose to collaborate as part of an influenza collaboration, where they are members of an established PCN or not, will be expected to sign up to an influenza ES vaccination collaboration agreement as described in this ES.
- 5.2 Each practice participating in this ES will:
 - 5.2.1 co-operate with others in so far as is reasonable, pursuant to this ES and/or the wider influenza vaccination programme, in a timely and effective manner
 - 5.2.2 comply with any reasonable request for information from the Commissioner (NHS England) relating to the provision of the services pursuant to this ES
 - 5.2.3 have regard to all relevant guidance published by the Commissioner (NHS England) or referenced within this ES (including but not limited to guidance published by the MHRA in relation to the movement of vaccines)
 - 5.2.4 comply with all clinical protocols giving explicit consideration to contra-indications and any guidance around concurrent administration of vaccinations
 - 5.2.5 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
 - 5.2.6 where relevant, ensure that it has in place suitable arrangements to enable the lawful sharing of data to support the delivery of the services, business administration and analysis activities.

6. Sub-contracting arrangements

- 6.1 The Commissioner (NHS England) acknowledges that to deliver the services pursuant to this ES, a practice may require the ability to sub-contract the delivery of the required clinical services to another practice 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.
- 6.2 Practices and their sub-contractor must make available, on request from the Commissioner (NHS England), any reasonable information relating to the sub-contracting arrangements and reporting information relating to the delivery of ES.
- 6.3 Practices and their sub-contractor must ensure that appropriate data management processes are in place which must include the recording of the administration of influenza vaccinations to ensure that payment can be made in accordance with this ES or in accordance with any alternative written agreement between the practice and the Commissioner (NHS England).
- 6.4 Insofar as the sub-contracting of the clinical services pursuant to this ES is necessary to deliver these services and is compliant with the primary medical services legal and contractual requirements, the Commissioner (NHS England) will not object to the sub-contracting. Practices must ensure that the sub-contractor is prohibited from sub-contracting the clinical matters.

7. Service Delivery Specification²

- 7.1 Vaccination should be given in sufficient time to ensure that patients are protected before the virus starts circulating. Practices should aim to schedule their influenza vaccination services to:
 - 7.1.1 match vaccine supply
 - 7.1.2 align with any JCVI guidance on the required interval between vaccinations, and where clinically relevant and in line with the Green Book the co-administration of vaccinations
 - 7.1.3 ensure that influenza vaccination is given in sufficient time to ensure patients are protected before influenza starts circulating. If an eligible patient presents late for influenza vaccination it is generally appropriate to still offer it. This is particularly important if it is a late influenza season or when an eligible patient under this ES is newly at risk. In the event that an eligible patient is in one of the at-risk groups and presents late in the flu season after all LAIV stock has expired, immunisation with an appropriate inactivated vaccine³ is an option. Clinicians should apply clinical judgement to assess the needs of patients for immunisation. The decision to vaccinate should take into account the level of flu-like illness in the community and the fact that the immune response to influenza vaccination takes about two weeks to fully develop.
- 7.2 Patients eligible for influenza vaccination under this ES are those patients:
 - 7.2.1 whose name is included in the practice's list of registered patients
 - 7.2.2 who are aged two or three years of age (but not aged less than two years of age or aged four years of age or over on 31 August 2022 (ie they were born on or after 1 September 2018 and on or before 31 August 2020), unless the influenza vaccination is contra-indicated.

 ² Practices must ensure they have read and understood all sections of this document as part of the implementation of this programme and to ensure understanding of the payment regime.
³ As defined by the influenza chapter in 'Immunisation against infectious disease' (the 'Green Book').

- 7.3 Practices will not be eligible for payment for the administration of influenza vaccinations outside the announced authorised cohorts.
- 7.4 Practices must ensure they offer influenza vaccinations to all eligible patients and:
 - 7.4.1 Practices are required to ensure, including to support the high uptake of influenza vaccinations and minimise wastage, where the patient is a registered patient of the practice, that they:
 - a) undertake a proactive call/recall if the patient is considered at-risk
 - b) undertake a proactive call if the patient is not considered at-risk with the aim of maximising uptake
 - c) reasonably co-operate with any national call/recall service
 - d) maintain clear records detailing how they have contacted (including called/recalled) patients.
 - 7.4.2 that influenza vaccinations are not administered where contraindicated where the patient has previously had a confirmed anaphylactic reaction to a previous dose of the vaccine, or to any component of the vaccine
 - 7.4.3 that influenza vaccinations are administered during the period of this ES
 - 7.4.4 that they comply with all law and relevant guidance (including that issued by JCVI, the Commissioner (NHS England), MHRA and/or UKHSA) as regards the administration of the influenza vaccination.
- 7.5 In complying with paragraph 7.4.1, practices must use at least one written communication (to include letters/SMS text messages) offering influenza vaccination to patients. practices must request details of the patient's ethnicity status if they have not previously provided this information to the practice and where provided by the patient or their carer, the practice must record the ethnicity information in the patient record.
- 7.6 Practices must ensure that all healthcare professionals who are involved in administering the vaccine:

- 7.6.1 have referred to the clinical guidance available including the influenza Chapter of the Green Book⁴ and Inactivated influenza vaccine information for healthcare practitioners⁵
- 7.6.2 do so in line with <u>the Green Book</u> and practices have a process in place to check any updates to the Green Book
- 7.6.3 have the necessary experience, skills and training, including training with regard to the recognition and initial treatment of anaphylaxis.
- 7.7 Practices must ensure that all vaccines are received, stored, prepared and subsequently transported (where appropriate, including if administered away from the practice premises, for example at home where the patient is housebound) in accordance with the relevant manufacturer's, UKHSA and NHS England's instructions and all associated guidance set out in the 'Storage distribution and disposal of vaccines chapter of the Green Book', including that all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that the readings are taken and recorded from that thermometer on all working days and that appropriate action is taken when readings are outside the recommended temperature.
- 7.8 Practices must have the ability and capacity to deliver this ES. Appointments should provide maximum flexibility for patients and should be available at a range of times across the week including during extended hours, such as evenings and weekends to maximise influenza vaccinations to eligible cohorts.
- 7.9 Practices must ensure that services delivered under this ES are accessible, appropriate and sensitive to the needs of all patients. No patient shall be excluded or experience particular difficulty in accessing and effectively using this ES due to a protected characteristic, as outlined in the Equality Act (2010) this includes Age, Disability, Gender Reassignment, Marriage and Civil Partnership, Pregnancy and Maternity, Race, Religion or Belief, Sex or Sexual Orientation.
- 7.10 Where the patient or parent/guardian has indicated they wish to receive the influenza vaccination but they are unable to attend at the practice (for

⁴ <u>https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book</u>

⁵ Annual flu programme - GOV.UK (www.gov.uk)

example because the medical condition of the patient is such that, in the reasonable opinion of the practice attendance on the patient is required and it would be inappropriate for the patient to attend the practice the practice must make all reasonable efforts to ensure the patient is vaccinated.

- 7.11 Practices should use the recommended licenced vaccine as set out in the annual <u>Flu letter</u> and the Green Book for influenza vaccination of patients. See Annex C.
- 7.12 Details of this programme and the wider seasonal influenza programme can be found in the annual <u>Flu letter</u>.
- 7.13 Details on the background, dosage, timings and administration of the influenza vaccination can be found in the <u>Green Book.</u>
- 7.14 Practices should ensure that the correct number of doses of vaccine are administered. Where two doses of vaccine are required, a failure to give both doses may leave a child incompletely protected. Conversely, where only one dose of vaccine is indicated, payment will not be made for any second doses that are inadvertently given. Patients aged two and three years at the time of influenza vaccination, who are in clinical risk groups and who have not received influenza vaccination previously, will require a second dose of the appropriate vaccine at least four weeks after the first dose.
- 7.15 The influenza chapter 'Immunisation against infectious disease' of the Green Book provides detailed descriptions of the eligible patients outlined above and guidance for healthcare workers on administering the influenza vaccine.

8. Monitoring, reporting and vaccine ordering

- 8.1 Practices delivering this ES should (if they have not already done so) sign up to receive the Primary Care Bulletin published by the Commissioner (NHS England) so key information in relation to the delivery of this ES can be communicated in a timely manner. Practices can sign up to the Primary Care Bulletin at: <u>NHS England » Primary Care bulletin</u>.
- 8.2 Practices must adhere to defined standards of record keeping ensuring that the influenza vaccination event is recorded in the medical record of the patient on the same day that it is administered where possible and shall include:
 - 8.2.1 any refusal of an offer of an influenza vaccination
 - 8.2.2 where an offer of influenza vaccination was accepted:
 - a) details of the informed consent to the influenza vaccination; (including persons that have consented on the patient's behalf and that person's relationship to the patient must also be recorded)
 - b) the batch number, expiry date and title of the vaccine
 - c) the date of administration of the influenza vaccination
 - d) when two or more vaccines are administered in close succession the route of administration and the injection site of each vaccine
 - e) any contra-indication to the influenza vaccination or immunisation
 - f) any adverse reactions to the influenza vaccination
 - g) one dose of LAIV (which is centrally supplied) is required for all patients who are not contra-indicated and should be recorded within the patient record.
- 8.3 Where an influenza vaccination is administered to a registered patient of the practice by a provider other than the practice and the patient's record is not automatically updated electronically, the practice must update the patient records on the same day that the vaccine is administered or on the day that notification is received from the other provider.

- 8.4 Practices must monitor and report all activity information in accordance with its primary medical services contract, relevant legislation and the monitoring and reporting standards as published by the Commissioner (NHS England).
- 8.5 Practices will be responsible for recording adverse events and providing the patient with information on the process to follow if they experience an adverse event in the future after leaving the vaccination site, including signposting the Yellow Card service. Practices will be expected to follow MHRA incident management processes in the case of a severe reaction.
- 8.6 Practices must ensure that they comply with all reporting and monitoring requirements to enable the Commissioner (NHS England) to calculate payments accurately.
- 8.7 Practices should ensure that they only use the relevant clinical codes included in the supporting business rules,⁶ or as set out in national guidance, and should also re-code patients where necessary. This will allow calculation of achievement and payment and for the Commissioner (NHS England) to audit payment and service delivery. Practices should refer to the supporting business rules⁷ to ensure that they have the most up-to-date information on management counts and clinical codes.
- 8.8 The Commissioner (NHS England) will monitor the provision of the services under this ES and will calculate payments under this ES using CQRS.
- 8.9 The LAIV vaccines for all patients aged two or three years of age (only) are centrally supplied as a nasal spray for children. When contra-indicated, a cell-grown quadrivalent inactivated influenza vaccine will be supplied. The LAIV and cell grown QIVc vaccines should be ordered online from ImmForm. These vaccines are supplied free of charge and will not be reimbursed as part of this NHS influenza Programme. QIVe is suitable to offer as a second option if QIVc is not available, but has not been procured by UKHSA for this age group and is therefore not centrally supplied.

⁶ http://content.digital.nhs.uk/gofesextractspecs

⁷ <u>https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections/quality-and-outcomes-framework-qof/quality-and-outcome-framework-qof-business-rules/enhanced-services-es-vaccination-and-immunisation-vi-and-core-contract-components-2022-2023</u>

- 8.10 Practices must ensure that all orders of vaccine are in line with national guidance, including adherence to any limits on stocks to be held during any period.
- 8.11 Practices will monitor and report all activity information via ImmForm on a monthly basis. As in previous years the activity information shall include a monthly count of patients who received a childhood influenza vaccination in the relevant month. This information will be used by the Commissioner (NHS England) and UKHSA for monitoring uptake achievement and national reporting. These figures are used for official statistics.

9. Payment and validation

- 9.1 Subject to compliance with this ES, a payment of £10.06 shall be payable to the practice for the administration of each influenza vaccination.
- 9.2 Practices will only be eligible for payment in accordance with this ES where all of the following requirements have been met and payment is conditional on:
 - 9.2.1 the patient who received the influenza vaccination(s) was a patient at the time the vaccine was administered, and all of the following apply:
 - a) the practice has only used the specified vaccines recommended in this ES and/or Commissioner (NHS England) guidance
 - b) the patient in respect of whom payment is being claimed was within an authorised cohort at the time the vaccine was administered, unless the exceptional circumstances set out at paragraph 7.3 apply
 - c) the practice has not received and does not expect to receive any payment from any other source in respect of the delivery of the influenza vaccination. Practices may claim a dispensing fee as set out in paragraph 16(2) and 16(3) of the NHS General Medical Services Statement of Financial Entitlements Direction 2021
 - d) where the vaccine is centrally supplied, no claim for reimbursement of vaccine costs or personal administration fee apply to those influenza vaccinations delivered to patients. This

does not apply to QIVe which has been purchased by the practice to administer as a second option to offer to those patients who are aged 2 and 3 years (as relevant to this ES) who are unsuitable for LAIV.

- e) the vaccines for the Childhood Seasonal influenza Immunisation Programme 2022/23 are outlined in the letter⁸ published on 16 July 2022. During the influenza season there may be additional advice from the Commissioner or UKHSA if there are issues with vaccine supply.⁹
- 9.2.2 the patient influenza vaccinations have been administered by the practice.
- 9.2.3 Practices submitting claims to the Commissioner (NHS England) for payment monthly wherever possible and practices must:
 - a) validate and submit a claim to the Commissioner (NHS England) for payment within six months of the date of the administration of the completing dose of the vaccine; and
 - b) ensure that claims submissions are validated to enable the Commissioner (NHS England) to correctly calculate the payment.
- 9.3 Payment will be made in respect of claims submitted by the last day of the month following the month the submitted claims are validated by the practice.
- 9.4 Practices must keep a record of the relevant circumstances to support reporting requirements and payment processes.
- 9.5 Payment under this ES, or any part thereof, is conditional on the practice satisfying the following conditions:
 - 9.5.1 they comply (and maintain compliance) with the requirements of this ES (including any variations and updates)
 - 9.5.2 they make available to the Commissioner (NHS England) any information under this ES which the Commissioner (NHS England)

⁸ <u>B1868_Reimbursable-vaccines-and-eligible-cohorts-for-the-2022-23-NHS-Seasonal-influenza-flu-vaccination-Progra.pdf (england.nhs.uk)</u>

⁹ Further details on the background, dosage, timings and administration of the vaccination can be found in the Flu letter.

needs and the practice either has or could be reasonably expected to obtain

- 9.5.3 they make any returns reasonably required of it (whether computerised or otherwise) to the payment system or CQRS or as otherwise may reasonably be required by the Commissioner (NHS England) (or on the Commissioner's [NHS England] behalf) and do so promptly and fully
- 9.5.4 all information supplied pursuant to or in accordance with this paragraph 9.5 is accurate.
- 9.6 If the practice does not satisfy any of the above conditions, the Commissioner (NHS England) may withhold payment of any, or any part of, an amount due under this ES that is otherwise payable.
- 9.7 If the Commissioner (NHS England) makes a payment to a practice under this ES and:
 - 9.7.1 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);
 - 9.7.2 the Commissioner (NHS England) 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
 - 9.7.3 the Commissioner (NHS England) is entitled to repayment of all or part of the money paid;

the Commissioner (NHS England) 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 (NHS England) that equivalent amount.

- 9.8 Where the Commissioner (NHS England) is entitled under this ES to withhold all or part of a payment because of a breach of a payment condition, and the Commissioner (NHS England) 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.
- 9.9 The Commissioner (NHS England) is responsible for post payment verification. This may include auditing claims (including supporting documentation/records) of practices to ensure that they meet the requirements of this ES.

Annex A

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

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

Provisions relating to practices which merge or are formed

A.4 Where two or more practices merge or a new primary medical services contract is awarded and as a result two or more lists of registered patients are combined, transferred (for example from a terminated practice) or a new list of registered patients is developed, the new practice(s) may enter into a new or varied arrangement with the Commissioner (NHS England) to provide this ES.

- A.5 In the event of a practice merger, the ES arrangements of the merged practices will be treated as having terminated (unless otherwise agreed with the Commissioner (NHS England)) and the entitlement of those practice(s) to any payment will be assessed on the basis of the provisions of paragraph 9 of this ES.
- A.6 The entitlement to any payment(s) of the practice(s), formed following a practice merger, entering into the new or varied arrangement for this ES, will be assessed and any new or varied arrangements that may be agreed in writing with the Commissioner (NHS England) will begin at the time the practice(s) starts to provide this ES under such arrangements.
- A.7 Where that new or varied arrangement is entered into and begins within 28 days of the new practice(s) being formed, the new or varied arrangements are deemed to have begun on the date of the new practice(s) being formed and payment will be assessed in line with this ES specification as of that date.
- A.8 Where the practice participating in the ES is subject to a practice merger and:
 - A.8.1 the application of the provisions set out above in respect of practice mergers would, in the reasonable opinion of the Commissioner (NHS England), lead to an inequitable result; or:
 - A.8.2 the circumstances of the split or merger are such that the provisions set out above in respect of practice mergers cannot be applied,

the Commissioner (NHS England) may, in consultation with the practice or practices concerned, agree to such payments as in the Commissioner's (NHS England) opinion are reasonable in all of the circumstances.

New contract awards

A.9 Where a new primary medical services contract is awarded by the Commissioner (NHS England) after the commencement of this ES, the practice may be offered the ability to opt-in to the delivery of this ES.

Annex B

Collaboration requirements for practices working in a PCN or a group of practices

- B.1 Practices may, under the terms of this ES and, where relevant, the Adult ES, collaborate to deliver influenza vaccinations to their patients. All practices which choose to collaborate as part of an influenza collaboration, where they are members of an established PCN or not, will be expected to sign up to an influenza ES vaccination collaboration agreement as described in this ES.
- B.2 Where this ES and, where relevant, the Adult ES sets out a requirement or obligation of a practice, each practice collaborating to deliver influenza vaccinations is responsible for ensuring the requirement or obligation is carried out on behalf of the collaborating practices.
- B.3 The practice, together with the other practices collaborating shall be considered joint and several owners of the vaccine which shall be shared and governed in accordance with the agreement between them and which must be documented in the influenza ES vaccination collaboration agreement.
- B.4 Each practice participating in an influenza collaboration to deliver this ES will:
 - B.4.1 co-operate with others in so far as is reasonable, including any other person responsible for the provision of services pursuant to this ES and/or the wider influenza vaccination programme, in a timely and effective way
 - B.4.2 openly, honestly and efficiently share information with other relevant parties including the practices in its influenza collaboration and outside of its influenza collaboration (where appropriate) that is relevant to the services, aims and objectives of this ES
 - B.4.3 adhere to the requirements in of this ES.
- B.5 Practices participating in an influenza collaboration may co-ordinate and deliver the influenza vaccinations at scale in line with the requirements set out in this ES and where relevant the Adult ES.

- B.6 The patients who attend for influenza vaccinations delivered by the influenza collaboration will attend what is deemed to be a temporary single medical practice for the purpose of regulation 3(8)(b) and 3A(1) of the Human Medicines Regulations 2012 (as amended).
- B.7 All practices participating in an influenza collaboration must agree the site(s) from which the influenza vaccinations under this ES and where relevant the Adult ES shall be delivered and which must be documented in the influenza ES vaccination collaboration agreement.
- B.8 All practices must have in place an influenza ES vaccination collaboration Agreement signed by all collaborating practices in advance of administering influenza vaccinations to patients under this arrangement as agreed by the Commissioner (NHS England). The influenza ES vaccination collaboration agreement must set out the clinical delivery model deployed by the practices (ie how clinics are delivered, and responsibility is shared between the practices) and as a minimum contains additional provisions in relation to the following:
 - B.8.1 appropriate arrangements for patient record sharing in line with data protection legislation
 - B.8.2 appropriate arrangements for reporting of activity data, vaccine stock, available capacity and minimising any wastage [as between the practices] and submission of required data to the Commissioner (NHS England)
 - B.8.3 appropriate arrangements for communicating with patients in accordance with paragraph 8.7
 - B.8.4 arrangements for any sharing and deployment of staff as agreed by the practices in relation to the efficient delivery of the services pursuant to this ES and where relevant the Adult ES
 - B.8.5 financial arrangements between the collaborating practices
 - B.8.6 arrangements in relation to use of the relevant premises (as required)
 - B.8.7 sub-contracting arrangements (as required)
 - B.8.8 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 9 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 influenza vaccinations by a practice to a person, including where they are not on the registered list of that practice

- B.8.9 appropriate arrangements to ensure that practices can identify, if appropriate, which patients receive influenza vaccinations under this ES and where relevant the Adult ES.
- B.9 The Commissioner (NHS England) has published a template influenza ES vaccination collaboration Agreement on the NHS England GP Contract webpage at <u>https://www.england.nhs.uk/gp/investment/gp-contract/</u>, which the collaborating practices may wish to use and adapt for the purpose of delivery this ES and where relevant the Adult ES.
- B.10 Collaborating practices may supply (under Regulation 19(4A) of the Human Medicines Regulations 2012 (as amended), a proportion of influenza vaccine to their temporary single medical practice. Collaborating practices must ensure that the influenza ES vaccination collaboration agreement documents the vaccine sharing arrangement between the practices and how this is governed. This must also document how the appropriate Collaborating practice(s) will claim reimbursement for:
 - B.10.1 any administered influenza vaccine supplied (where relevant and not provided free of charge under this ES); and
 - B.10.2 any dispensing fee (where eligible).
- B.11 Collaborating practices will need to plan service delivery arrangements in line with their own stock forecasting and ordering arrangements including:
 - B.11.1 Planning clinics according to expected vaccine supply
 - B.11.2 coordinating required trained staff
 - B.11.3 receiving and safely storing supply

B.11.4 amending clinic schedules if required and undertaking timely communication of any changes to patients.

Annex C

Summary table of which influenza vaccines to offer to children in this ES and included in the national influenza immunisation programme as defined in the Flu letter¹⁰ and Green Book¹¹

Eligible Group	Type of influenza vaccine
Aged two or three years on 31 August 2022	Offer LAIV. If LAIV is contraindicated (or it is otherwise unsuitable) offer QIVc*
At-risk children aged two to under 18 years	Offer LAIV. If LAIV is contraindicated (or it is otherwise unsuitable) offer QIVc*

*QIVe is suitable to offer as a second option but has not been procured by UKHSA for this age group.

 ¹⁰ <u>https://assets.publishing.servicegov.uk/government/uploads/system/uploads/attachment_data/file/</u>
<u>1070494/Tripartite-annual-flu-letter-2022-to-2023.pdf</u>
¹¹ https://www.gov.uk/government/publications/influenza-the-green-book-chapter-19

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