

WG24-38

THE NATIONAL HEALTH SERVICE (WALES) ACT 2006

The Primary Care (Contracted Services: Immunisations) (RSV) Directions 2024

Made 22 August 2024

Coming into force 1 September 2024

The Welsh Ministers, in exercise of the powers conferred on them by sections 10, 12(3) and 203(9) and (10) of the National Health Service (Wales) Act 2006(1), give the following Directions.

Title, application and coming into force

1.—(1) The title of these Directions is the Primary Care (Contracted Services: Immunisations) (RSV) Directions 2024.

(2) These Directions are given to Local Health Boards.

(3) These Directions come into force on 1 September 2024.

Interpretation

2. In these Directions—

“the Act” (“*y Ddeddf*”) means the National Health Service (Wales) Act 2006;

“cluster” (“*clwstwr*”) means a group of local service providers involved in health and care who have agreed to collaboratively work together to deliver primary medical services across a specified geographical area;

“cluster lead practice” (“*practis arweiniol clwstwr*”) means a general medical practitioner that has agreed to provide the Scheme to its

(1) 2006 c. 42. There are amendments to sections 10 and 203 which are not relevant to these Directions.

registered patients, and to the registered patients of a general medical practitioner in its cluster that is not an engaged provider, and which the Local Health Board agrees will be a cluster lead practice;

“corporate optician” (“*optegydd corfforedig*”) means a body corporate registered in the register maintained under section 9 of the Opticians Act 1989⁽¹⁾ (list of bodies corporate carrying on business as opticians), which is carrying on business as an optometrist, and for the purpose of this definition, “optometrist” has the meaning given in section 36 of that Act⁽²⁾ (interpretation);

“dentist” (“*deintydd*”) means a dental practitioner—

- (a) who is registered in the dentists register referred to in section 14(1) of the Dentists Act 1984⁽³⁾, and
- (b) whose name is included in a dental performers list prepared by a Local Health Board under regulation 3 of the National Health Service (Performers Lists) (Wales) Regulations 2004⁽⁴⁾;

“Drug Tariff” (“*Tariff Cyffuriau*”) has the meaning given to it in regulation 55 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020⁽⁵⁾ (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors);

“engaged provider” (“*darparwr sydd wedi ei gymryd ymlaen*”) means a dentist, general medical practitioner (whether acting for itself, as a cluster lead practice, or on behalf of another practice or group of practices), optician, or NHS pharmacist that agrees with a Local Health Board to provide services under the Scheme pursuant to an arrangement made in accordance with paragraph 4;

“GDS contractor” (“*contractwr GDC*”) means a person who is a party to a contract with a Local Health Board pursuant to section 57 of the Act;

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- (1) 1989 c. 44. Section 9 was amended by article 10 of S.I. 2005/848, paragraph 44 of Schedule 4 to the Co-operative and Community Benefit Societies Act 2014 (c. 14), and paragraph 37 of Schedule 1 to the Credit Unions and Co-operative and Community Benefit Societies Act (Northern Ireland) 2016 (c. 16).
 - (2) Section 36 was amended by paragraph 8 of Schedule 1 to S.I. 2005/848; there are other amendments to section 36 which are not relevant to these Directions.
 - (3) 1984 c. 24. Section 14 was amended by article 6 of S.I. 2005/2011, regulation 111 of S.I. 2007/3101, and paragraph 4 of Schedule 3 to S.I. 2019/593.
 - (4) S.I. 2004/1020 (W. 117). Regulation 3 was amended by regulation 3 of S.I. 2006/945 (W. 94).
 - (5) S.I. 2020/1073 (W. 241).

“general medical practitioner” (“*ymarferydd meddygol cyffredinol*”) means a medical practitioner whose name is included in—

- (a) the General Practitioner Register kept by the General Medical Council under section 34C of the Medical Act 1983⁽¹⁾, and
- (b) a medical performers list prepared by a Local Health Board under regulation 3 of the National Health Service (Performers Lists) (Wales) Regulations 2004;

“GMS contractor” (“*contractwr GMC*”) means a person who is a party to a contract with a Local Health Board pursuant to section 42 of the Act;

“GOS contractor” (“*contractwr GOC*”) means a person who is included in a Local Health Board’s ophthalmic list and provides primary ophthalmic services as part of the health service in Wales under the National Health Service (Ophthalmic Services) (Wales) Regulations 2023⁽²⁾;

“health care professional” (“*proffesiynolyn gofal iechyd*”) means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002⁽³⁾;

“NHS pharmacist” (“*fferyllydd GIG*”) means a person whose name is included in a pharmaceutical list under regulation 10 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020⁽⁴⁾ (preparation and maintenance of pharmaceutical lists), for the provision of pharmaceutical services in particular by the provision of drugs, and who is—

- (a) registered in Part 1 of the General Pharmaceutical Council Register⁽⁵⁾, or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976⁽⁶⁾, or

(1) 1983 c. 54. Section 34C was inserted by article 4 of, and paragraph 10 of Schedule 1 to, the General and Specialist Medical Practice (Education, Training and Qualifications) Order 2010 (S.I. 2010/234).

(2) S.I. 2023/1053 (W. 179).

(3) 2002 c. 17. Section 25(3) was amended by article 68 of, and paragraph 10(2) of Schedule 4 to, the Pharmacy Order 2010 (S.I. 2010/231); section 127 of, and paragraph 17(2) and (3) of Schedule 10 to, the Health and Social Care Act 2008 (c. 14); section 230(1) of, and paragraph 56(b) of Schedule 15 to, the Health and Social Care Act 2012 (c. 7); section 56 of, and paragraph 2(2) of Schedule 4 to, the Children and Social Work Act 2017 (c. 16).

(4) S.I. 2020/1073 (W. 241).

(5) Maintained under article 19 of the Pharmacy Order 2010 (establishment, maintenance of and access to the Register). Article 19 was amended by regulation 3 of, and paragraph 9 of Schedule 2 to, S.I. 2019/593.

(6) S.I. 1976/1213 (N.I. 22). Article 6 was amended by regulation 5 of S.I. 2008/192, and regulation 2 of, and paragraph 6 of the Schedule to, S.I. 2019/585. Article 9 was

(b) lawfully carrying on a retail pharmacy business in accordance with section 69 of the Medicines Act 1968(1);

“NHS services” (“*gwasanaethau GIG*”) means ophthalmic services, pharmaceutical services, primary dental services or primary medical services (as appropriate to the relevant engaged provider) provided pursuant to Parts 4 to 7 of the Act as part of the health service in Wales;

“NHS Wales Shared Services Partnership” (“*Partneriaeth Cydwasanaethau GIG Cymru*”) means the Velindre National Health Service Trust Shared Services Committee established by regulation 3 of the Velindre National Health Service Trust Shared Services Committee (Wales) Regulations 2012(2);

“optician” (“*optegydd*”) means a person who is—

(a) registered in the register of optometrists maintained under section 7 of the Opticians Act 1989 (register of opticians), or

(b) a corporate optician;

“other NHS bodies” (“*cyrff eraill y GIG*”) means—

(a) a National Health Service Trust established in accordance with section 18(1) of the Act, or

(b) a Special Health Authority established in accordance with section 22(1) of the Act(3);

“Public Health Wales” (“*Iechyd Cyhoeddus Cymru*”) means the Public Health Wales National Health Service Trust established by article 2 of the Public Health Wales National Health Service Trust (Establishment) Order 2009(4);

“registered patient” (“*claf cofrestredig*”) means—

(a) a person who is recorded by the Local Health Board as being on a general medical practitioner’s list of patients, or

(b) a person whom the general medical practitioner has accepted for inclusion on its list of patients, whether or not notification of that acceptance has been received by the Local Health Board and who has not been

(1) amended by regulation 2 of, and paragraph 13 of the Schedule to, S.I. 2019/585, and article 10 of S.I. 2022/849. 1968 c. 67. Section 69 was amended by section 1 of, and Part XII of Schedule 1 to, the Statute Law (Repeals) Act 1993 (c. 50); article 67 of, and paragraph 2 of Schedule 1 to, S.I. 2007/289; article 68 of, and paragraph 1 of Schedule 4 to, S.I. 2010/231; regulation 3 of, and paragraph 4 of Schedule 2 to, S.I. 2019/593.

(2) S.I. 2012/1261 (W. 156).

(3) There are amendments to section 22, but none are relevant to these Directions,

(4) S.I. 2009/2058 (W. 177).

notified by the Local Health Board as having ceased to be on that list,

and who is eligible for vaccination services under the Scheme as they fall within an eligible group specified in paragraph 2 of the relevant specification;

“relevant specification” (*“manyleb berthnasol”*) means the specification contained in a Schedule to these Directions;

“RSV” (*“RSV”*) means respiratory syncytial virus;

“Scheme” (*“Cynllun”*) means the Primary Care Contracted Services: Immunisations Scheme for RSV established by a Local Health Board in accordance with paragraph 3;

“Statement of Financial Entitlements” (*“Datganiad ar Hawlogaethau Ariannol”*) means any directions given by the Welsh Ministers pursuant to—

- (a) section 45 of the Act in relation to payments to be made by a Local Health Board to a GMS contractor, or
- (b) section 60 of the Act in relation to payments to be made by a Local Health Board to a GDS contractor;

“Statement of Remuneration” (*“Datganiad o Dâl”*) means any determination made by the Welsh Ministers pursuant to section 76 of the Act, and regulation 31 of the National Health Service (Ophthalmic Services) (Wales) Regulations 2023, in relation to payments to be made by a Local Health Board to a GOS contractor;

“Welsh Immunisation System” (*“System Imiwneiddio Cymru”*) means the information system for the management, distribution and reporting of vaccinations.

Establishment of a Primary Care Contracted Services: Immunisations Scheme for RSV

3.—(1) Each Local Health Board must establish, operate and, as appropriate, revise a Scheme in accordance with these Directions and the relevant specification.

(2) The underlying purpose of the Scheme is to enable the provision of services to administer RSV vaccinations and immunisations as part of the health service in Wales by dentists, general medical practitioners, opticians and NHS pharmacists.

Primary Care Contracted Services: Immunisations Scheme for RSV

4.—(1) Each Local Health Board must enter into arrangements for the provision of services under the Scheme—

- (a) in the first instance, with GMS contractors—
 - (i) in relation to their registered patients;
 - (ii) as a cluster lead practice, in relation to the registered patients of the cluster lead practice and the registered patients of those general medical practitioners, if any, in its cluster that have not agreed within such time period as the Local Health Board requires, to deliver the Scheme to their registered patients pursuant to sub-paragraph (i);
 - (iii) in relation to the registered patients of another general medical practitioner or group of general medical practitioners, where that general medical practitioner has agreed to deliver the Scheme pursuant to sub-paragraph (i), subject to the agreement of the other general medical practitioner or group of general medical practitioners;
- (b) where the registered patients of a general medical practitioner will not receive the services under the Scheme from GMS contractors under paragraph (a), the Local Health Board must make arrangements to ensure the provision of the services to the registered patients of that general medical practitioner by providing the services itself or arranging for the delivery of those services by any other engaged provider.

(2) Where the Local Health Board makes arrangements to provide the services under the Scheme itself, or arranges for the delivery of those services by any other engaged provider, the services must be provided as close to the practice premises of that general medical practitioner as is reasonably practicable.

(3) An arrangement made between a cluster lead practice and a Local Health Board in accordance with sub-paragraph (1)(a)(ii) must include a requirement that each engaged provider co-operates with the other engaged providers and the cluster lead practice in its cluster in order for the cluster lead practice to complete, by such date as the Local Health Board requires, a plan setting out the arrangement for the delivery of the services under the Scheme to all registered patients of the general medical practitioners across the cluster.

(4) Sub-paragraph (3) applies regardless of whether a general medical practitioner who is a member of the cluster is an engaged provider or not.

(5) For the purposes of sub-paragraph (3)—

- (a) where there is only one engaged provider, and it is the cluster lead practice, it is responsible for completing that plan;
- (b) where there is no cluster lead practice, and all the general medical practitioners in the cluster are engaged providers, they are all responsible for completing that plan.

(6) Where arrangements are made between a Local Health Board and an engaged provider, those arrangements must include—

(a) a requirement that the engaged provider—

- (i) takes account of these Directions and complies with the relevant specification;
- (ii) maintains and keeps up to date a record on the Welsh Immunisation System of all persons receiving the services under the Scheme;

(iii) provides the services required by the relevant specification and, as appropriate, in line with the plan specified in sub-paragraph (3) above or sub-paragraph (iv) below;

(iv) completes to the satisfaction of the Local Health Board, prior to the provision of any services under the Scheme and by such date as the Local Health Board requires, a plan setting out the arrangements for the delivery of the services under the Scheme by the engaged provider including, as a minimum—

(aa) the dates and times when services under the Scheme will be delivered,

(bb) how the engaged provider will continue to provide, without interruption, its NHS services whilst it is a party to an arrangement under the Scheme, and

(cc) such other detail or assurances that the Local Health Board may reasonably request from the engaged provider;

(b) a requirement that the engaged provider takes all reasonable steps to ensure that the Welsh Immunisation System is updated as soon as reasonably practicable after a person has received a vaccination, and by no later than

the end of the day on the day on which a vaccination is administered;

- (c) a requirement that the engaged provider must use the Welsh Immunisation System for the following purposes and to record the following information, in particular, on the Welsh Immunisation System—
 - (i) any refusal of an offer of vaccination, or
 - (ii) where an offer of vaccination was accepted—
 - (aa) details of the consent to the vaccination or immunisation (where a person has consented on another person's behalf, the relationship to the person receiving the vaccine must also be recorded),
 - (bb) the batch number, expiry date and title of the vaccine,
 - (cc) the dose of the vaccine administered,
 - (dd) the name of the person drawing up the vaccine,
 - (ee) the name of the person administering the vaccine (if different to the person in (dd)),
 - (ff) the date and time the vaccine was administered,
 - (gg) where more than one vaccine is administered, the route of administration and the injection site of each dose of the vaccine,
 - (hh) any contraindications to the vaccine or immunisation,
 - (ii) any immediate adverse reactions to the vaccine or immunisation,
 - (jj) the refrigerator temperature(s) where vaccines are stored, twice daily (at the start and the end of the day) on all working days, in accordance with national guidance,
 - (kk) if required, to supply Public Health Wales with information on persons they have administered a vaccine to under the Scheme, via automated data extraction, for the purpose of monitoring local and national uptake,
 - (ll) to supply NHS Wales Shared Services Partnership with information on persons who have

received a vaccine under the Scheme, for payment and, if required, post payment verification purposes, and

- (mm) to provide data, to the cluster lead practice of a cluster (where applicable), Local Health Boards, other NHS bodies, and Welsh Government, when required;
- (d) a requirement that the engaged provider must adhere to the current guidance in chapter 3 (Storage, distribution and disposal of vaccines) of the latest edition of the “Green Book”(1) at the time of administering the vaccination;
- (e) a requirement that the engaged provider—
 - (i) ensures consistent coding for capture of data and compliance with relevant information governance legislation;
 - (ii) ensures that each health care professional involved in the provision of services under the Scheme has the necessary skills, training, competence and experience in order to provide those services;
 - (iii) ensures that each health care professional involved in the provision of services under the Scheme completes any relevant training provided by Public Health Wales and that the engaged provider keeps a record to confirm that each health care professional has undertaken the relevant training prior to participating in the administration of vaccinations;
 - (iv) ensures each health care professional involved in the provision of services under the Scheme completes relevant continuing professional development (CPD) activity through, for example, regular educational updates, attendance at relevant courses provided by Local Health Boards, as well as self-directed learning, to be able to demonstrate they have adequate knowledge and skills through their annual appraisal and revalidation;
 - (v) ensures that each health care professional involved in the provision of services under the Scheme is adequately

(1) “Green Book” means the publication ‘Immunisation against infectious disease’, available at: <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

- indemnified/insured for any liability arising from the work performed;
- (vi) supplies its Local Health Board with such information as the Local Health Board may reasonably request for the purposes of monitoring the performance of obligations under the Scheme and, as appropriate, the cluster's performance in relation to the plan specified in sub-paragraph (3) or the engaged provider's performance in relation to the plan specified in sub-paragraph (6)(a)(iv);
 - (vii) gives its Local Health Board at least the minimum notice period stated in the relevant specification, in writing, prior to terminating their arrangement to provide services under the Scheme;
- (f) payment arrangements for an engaged provider which must provide for it to be able to claim in accordance with paragraph 10 of the relevant specification a payment of—
- (i) £10.03 per each dose of RSV vaccine administered, and
 - (ii) in addition to the fee specified in sub-paragraph (i), for the period beginning with 1 September 2024 and ending with 31 August 2025, £1.00 for each dose of RSV vaccine administered.

(7) Where the Local Health Board delivers the Scheme pursuant to an arrangement in accordance with sub-paragraph (1)(b), the Local Health Board must ensure that sub-paragraph (6) applies to such arrangements as it would to an engaged provider.

Eligibility for and conditions of payment

5.—(1) A dentist, general medical practitioner, optician or NHS pharmacist is only eligible for a payment for provision of services under the Scheme in circumstances where the following conditions are met—

- (a) they are a GMS contractor or any other engaged provider;
- (b) if they are an engaged provider other than a GMS contractor, the person in respect of whom the payment for the administration of an RSV vaccine is claimed was allocated to the engaged provider by the Local Health Board with whom the engaged provider has an agreement to provide services under the Scheme;
- (c) the engaged provider does not receive any payment from any other source in respect of an RSV vaccine, but if the engaged provider

does receive payments from other sources in respect of any person, the Local Health Board must consider whether to recover any payment made under the Scheme in respect of that person pursuant to paragraph 7 (overpayments and withheld amounts);

- (d) if, for the purpose of creating a clinical record of immunisation, in respect of each person for which a payment under the Scheme is claimed, the engaged provider has supplied the Local Health Board via the Welsh Immunisation System with—
 - (i) the name of the person,
 - (ii) the date of birth of the person,
 - (iii) the NHS number of the person (if known), and
 - (iv) the date on which the RSV vaccine has been administered;
- (e) the engaged provider creates the clinical record on the Welsh Immunisation System by the end of the day on the day on which a vaccine is administered.

(2) The Local Health Board may request from an engaged provider any information which the Local Health Board does not have but needs, and the engaged provider either has or could be reasonably expected to obtain, in order for the Local Health Board to form an opinion on whether the engaged provider is eligible for payment under the provisions of the Scheme.

(3) Subject to paragraph 7, the Local Health Board may, in appropriate circumstances, withhold payment of any, or any part of, payments due under the Scheme if an engaged provider breaches any of these conditions.

Payment under the Scheme

6.—(1) Where an engaged provider satisfies requirements under paragraph 5, the engaged provider will receive an automatic payment based on the information recorded on the Welsh Immunisation System in respect of each person who has received a vaccine and the activity of the engaged provider will be captured by NHS Wales Shared Services Partnership as at the tenth day of each calendar month.

(2) Any amount payable in accordance with sub-paragraph (1) falls due following the expiry of 14 days after the activity is captured under sub-paragraph (1)—

- (a) in the case of a GDS contractor, on the next date when the GDS contractor's payable monthly Annual Contract Value Payment falls due in accordance with the relevant Statement of Financial Entitlements;

- (b) in the case of a GMS contractor, on the next date when the GMS contractor's Global Sum monthly payment falls due in accordance with the relevant Statement of Financial Entitlements;
- (c) in the case of a GOS contractor, on the date in the next month when the GOS contractor's General Ophthalmic Services monthly reimbursement falls due in accordance with the Statement of Remuneration;
- (d) in the case of a NHS pharmacist, on the next date when the NHS pharmacist receives any other payments due under the Drug Tariff.

(3) The Local Health Board must ensure that the receipt and payment in respect of any automatic payments made pursuant to sub-paragraph (1) are properly recorded and that each such payment has a clear audit trail.

Overpayments and withheld amounts

7.—(1) Subject to sub-paragraph (2), the Local Health Board may, in the circumstances set out in sub-paragraph (3), recover money paid to an engaged provider under the Scheme by deducting an equivalent amount from any payment payable under the Scheme, or any other payment payable to an engaged provider by virtue of its provision of NHS services.

(2) Where no such deduction as described under sub-paragraph (1) can be made, it is a condition of the payments made pursuant to the Scheme that the engaged provider must pay to the Local Health Board that equivalent amount.

(3) The circumstances referred to in sub-paragraph (1) are where a Local Health Board makes a payment to an engaged provider pursuant to the Scheme and—

- (a) the engaged provider 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),
- (b) the Local Health Board 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
- (c) the Local Health Board is entitled to repayment of all or part of the money paid.

(4) Where a Local Health Board is entitled pursuant to sub-paragraph (1) to withhold all or part of a payment because of a breach of a payment condition, and the Local Health Board does so or recovers the

money by deducting an equivalent amount from another payment payable under the Scheme, or any other payment payable to an engaged provider by virtue of its provision of NHS services, it may, where it sees fit to do so, reimburse the engaged provider the amount withheld or recovered, if the breach is cured.

Underpayments and late payments

8.—(1) If the full amount of a payment that is payable under the Scheme has not been paid before the date on which the payment falls due, once it falls due, it must be paid promptly unless—

- (a) this is with the consent of the engaged provider, or
- (b) the amount of, or entitlement to, the payment, or any part thereof, is in dispute.

(2) If the engaged provider's entitlement to the payment is not in dispute but the amount of the payment is in dispute, then once the payment falls due, pending the resolution of the dispute, the Local Health Board must—

- (a) pay to the engaged provider, promptly, an amount representing the amount that the Local Health Board accepts that the engaged provider is at least entitled to, and
- (b) thereafter pay any shortfall promptly, once the dispute is finally resolved.

(3) However, if an engaged provider has—

- (a) not claimed a payment to which it would be entitled under the Scheme if it claimed the payment, or
- (b) claimed a payment to which it is entitled under the Scheme but a Local Health Board is unable to calculate the payment until after the payment is due to fall due because it does not have the information it needs in order to calculate that payment (all reasonable efforts to obtain the information having been undertaken),

that payment is (instead) to fall due on the first working day of the month after the month during which the Local Health Board obtains the information it needs in order to calculate the payment.

Payments on account

9.—(1) Subject to sub-paragraph (2), where a Local Health Board and the engaged provider agree, the Local Health Board must pay to an engaged provider on account any amount that is—

- (a) the amount of, or a reasonable approximation of the amount of, a payment that is due to fall due under the Scheme, or

- (b) an agreed percentage of the amount of, or a reasonable approximation of the amount of, a payment that is due to fall due under the Scheme, and if that payment results in an overpayment in respect of the payment, paragraph 7 applies.

(2) The Local Health Board may withdraw its agreement under sub-paragraph (1) where—

- (a) it is reasonable to do so, and
- (b) it has given the engaged provider reasonable notice of its withdrawal.

Post payment verification

10. Post payment verification⁽¹⁾ may apply to the provision of services under the Scheme.

Dispute resolution

11.—(1) In the case of any dispute arising out of, or in connection with, the Scheme, the engaged provider and the Local Health Board must make every reasonable effort to communicate and cooperate with each other with a view to resolving the dispute, before referring the dispute for consideration and determination to the Welsh Ministers in accordance with the Scheme dispute resolution procedure (or, where applicable, before commencing court proceedings) specified in sub-paragraphs (2) to (15).

(2) The procedure specified in the following sub-paragraphs applies in the case of any dispute arising out of or in connection with the Scheme which is referred to the Welsh Ministers.

(3) Any party wishing to refer a dispute as mentioned in sub-paragraph (2) must send to the Welsh Ministers a written request for dispute resolution which must include or be accompanied by—

- (a) the names and addresses of the parties to the dispute,
- (b) a copy of any arrangement made under the Scheme, and
- (c) a brief statement describing the nature and circumstances of the dispute.

(4) Any party wishing to refer a dispute as mentioned in sub-paragraph (2) must send the request under sub-paragraph (3) within a period of 3 years beginning with the date on which the matter giving rise to the dispute happened or should reasonably have come to the attention of the party wishing to refer the dispute.

(1) For more information on post payment verification, please see: <https://nwssp.nhs.wales/ourservices/primary-care-services/general-information/post-payment-verification-ppv/>

(5) The Welsh Ministers may determine the matter themselves or, if the Welsh Ministers consider it appropriate, appoint a person or persons to consider and determine it.

(6) Before reaching a decision as to who should determine the dispute, under sub-paragraph (5), the Welsh Ministers must, within 7 days beginning with the date on which a matter under dispute was referred to them, send a written request to the parties to make in writing, within a specified period, any representations which they may wish to make about the matter under dispute.

(7) The Welsh Ministers must give, with the notice given under sub-paragraph (6), to the party other than the one which referred the matter to dispute resolution, a copy of any document by which the matter was referred to dispute resolution.

(8) The Welsh Ministers must give a copy of any representation received from a party to the other party and must in each case request (in writing) a party to whom a copy of the representations is given to make, within a specified period, any written observations which it wishes to make on those representations.

(9) Following the end of the specified period for making representations under sub-paragraph (6) or (8), or if earlier, on receipt of any such representations from the parties, the Welsh Ministers must, if they decide to appoint a person or persons to hear the dispute—

- (a) inform the parties in writing of the name of the person or persons whom it has appointed, and
- (b) provide to the person or persons so appointed any documents received from the parties under sub-paragraph (3), (6) or (8).

(10) For the purpose of assisting the adjudicator in the consideration of the matter, the adjudicator may—

- (a) invite representatives of the parties to appear before the adjudicator to make oral representations either together or, with the agreement of the parties, separately, and may in advance provide the parties with a list of matters or questions to which the adjudicator wishes them to give special consideration, or
- (b) consult other persons whose expertise the adjudicator considers will assist in the consideration of the matter.

(11) Where the adjudicator consults another person under sub-paragraph (10)(b), the adjudicator must notify the parties accordingly in writing and, where the adjudicator considers that the interests of any party might be substantially affected by the result of the consultation, the adjudicator must give to the parties such opportunity as the adjudicator considers

reasonable in the circumstances to make observations on those results.

(12) In considering the matter, the adjudicator must consider—

- (a) any written representations made in response to a request under sub-paragraph (6), but only if they are made within the specified period;
- (b) any written observations made in response to a request under sub-paragraph (8), but only if they are made within the specified period;
- (c) any oral representations made in response to an invitation under sub-paragraph (10)(a);
- (d) the results of any consultation under sub-paragraph (10)(b);
- (e) any observations made in accordance with an opportunity given under sub-paragraph (11).

(13) Subject to the other provisions within this paragraph and to any agreement by the parties, the adjudicator has wide discretion in determining the procedure of the dispute resolution to ensure the just, expeditious, economical and final determination of the dispute.

(14) The determination of the adjudicator and the reasons for it must be recorded in writing and the adjudicator must give notice of the determination (including the record of the reasons) to the parties.

(15) In this paragraph—

“specified period” means such period as the Welsh Ministers specify in a request, being not less than 2, nor more than 4, weeks beginning with the date on which the notice referred to is given, but the Welsh Ministers may, if they consider that there is good reason for doing so, extend any such period (even after it has expired) and, where they do so, a reference in this paragraph to the specified period is to the period as so extended.



Sioned Rees
Director, Public Health Directorate, under the
authority of the Cabinet Secretary for Health and
Social Care, one of the Welsh Ministers

22 August 2024

Primary Care Contracted Services: Immunisations (Annual RSV Vaccination) Specification

Introduction

Vaccination has long been a crucial part of NHS delivery to protect citizens and communities.

The [National Immunisation Framework \(NIF\)](#) sets out the ambition to integrate all our vaccination programmes, using the lessons learned from the pandemic to transition into an improved business as usual arrangement.

The Cabinet Secretary for Health and Social Care agreed to the advice of the Joint Committee on Vaccination and Immunisation (JCVI) that an Respiratory Syncytial Virus (RSV) vaccination programme should be stood up to protect infants and individuals aged 75-79 years who are most susceptible to the disease. There are now several licensed products that offer protection against RSV with more products expected to be licensed in future years. Following a successful procurement exercise undertaken by UKHSA, licensed vaccine products are now available to use in Wales.

Successful delivery of the RSV Vaccination Programme will require collaboration across primary care and the wider health system to maximise our use of resources, and to ensure timely and safe vaccine deployment which drives high levels of uptake.

This Specification for the Primary Care Contracted Services: Immunisations (“PCCS:I”) scheme specifically relates to the delivery of the RSV vaccine to eligible individuals by Primary Care providers, defined for the purpose of this specification as “engaged providers”.

Engaged providers should refer to the relevant Welsh Health Circulars(s) (WHC) in providing this service.

Background

Respiratory syncytial virus (RSV) is an enveloped RNA virus, in the same family as the human parainfluenza viruses (HPV) and mumps and measles viruses.

A typical RSV season in the UK starts in October, peaks in December and declines by March and it can contribute to the significant pressures the NHS faces during winter. The introduction of vaccination programmes to protect against RSV will protect those at risk of harm of the disease and alleviate pressure on the NHS.

Advice to Welsh Government contained in a programme planning feasibility study from Vaccination Programme Wales (NHS Executive) supports the viability of delivering, via primary care, both the older adult programme and maternal vaccination, where the 28-week antenatal appointment takes place on GP premises, and where requested by the midwife or pregnant woman.

1. Scheme aim

This PCCS:I provides the mechanism for Primary Care providers to enter into a commissioning arrangement with their Local Health Board (“the relevant Local Health Board”) to provide the NHS RSV vaccination programme.

2. Eligible cohorts

Eligibility for immunisation and prioritisation of groups will be determined by the Welsh Government, based on the advice of the JCVI, and confirmed via a Welsh Health Circular from the Chief Medical Officer.

This Specification only relates to those specific groups eligible and commissioned by the contracting Local Health Board. Vaccination outside of the specified eligible groups will not result in a payment under this PCCS:I.

Scheduling of appointments will be via the engaged providers established booking system. Where a provider does not maintain a patient list then an opportunistic offer will be appropriate.

(a) Older adults—

- (i) the relevant Local Health Board, with the engaged provider, will develop a proactive and preventative approach to offering the RSV vaccines. **Engaged providers are expected to agree a plan with the relevant Local Health Board which includes arrangements for robust call and reminder systems to contact individuals within older adult eligible cohorts**, with the aims of—

- (aa) maximising vaccination uptake in the interests of those persons, and

as specified in any public health targets and the WHC,

- (bb) accepting any order in which eligible groups will be vaccinated and timescale over which vaccines will be administered, and
- (cc) ensuring patient records are updated to reflect the vaccination status, where a GP Practice is vaccinating a patient on behalf of another practice through a pre agreed arrangement with the health board.

(b) **Maternal programme—**

- (i) where possible, the maternal vaccine will be administered through maternity settings in secondary care and community hubs (providing that a vaccinator is available at the 28-week antenatal appointment). Where antenatal appointments take place at GP practices, vaccination should be facilitated on these premises at the 28-week appointment or via a follow-up appointment;
- (ii) the engaged provider **will not be required to provide a proactive offer or call/recall for maternal RSV vaccination for infant protection**, but working in collaboration with the midwifery service, the engaged provider should facilitate a vaccination appointment for pregnant women on request. Vaccination can be reimbursed when a pregnant woman presents at the engaged provider as advised by the health board midwifery team/or is self-presenting.

3. Model for delivery

Engaged providers must ensure that delivery of core services is not compromised by activity delivered under this PCCS:I. Opportunistic vaccination in line with the principles of ‘Making Every Contact Count’ is encouraged, however, activity under this PCCS:I must not be in lieu of, or impede the delivery of, unified services under the GMS Unified Contract.

- (a) Any person who administers a vaccine under this PCCS:I must do so in accordance with the Primary Care (Contracted Services: Immunisations) (RSV) Directions 2024 (“the relevant Directions”), and this PCCS:I Specification, after obtaining consent, and following guidance in the [Green Book](#) and relevant Welsh Health Circulars issued by the

Chief Medical Officer, and any other relevant guidance relating to the administration of the vaccine, which is given from time to time.

- (b) The engaged provider must ensure—
 - (i) that all persons who receive a vaccine under this PCCS:I are eligible in accordance with current clinical guidance,
 - (ii) all staff are aware of the groups eligible for vaccination under this Specification and the sequence for delivery,
 - (iii) informed consent is obtained by a registered healthcare professional,
 - (iv) the patient’s consent to the vaccination (or name of the person who gave consent to the vaccination and that person’s relationship to the patient) is recorded in the patient’s record in accordance with law and guidance,
 - (v) consent obtained for the purposes of paragraph 3(b)(iii) of this Specification is recorded (as appropriate) for any necessary information sharing with the relevant Local Health Board, in accordance with data protection legislation and guidance, and
 - (vi) the recommended vaccine, and the correct dosage of a RSV vaccine, is administered as clinically appropriate and in keeping with vaccination time limitations and expiry dates.

4. Conditions for service delivery

An engaged provider may only participate in this PCCS:I to provide services in accordance with this Specification, if all of the following conditions are met—

- (a) all persons who are involved in the administration of vaccinations must—
 - (i) have the necessary skills, training and (where applicable) accreditation, competence and experience to provide the service,
 - (ii) be adequately trained in administration of vaccinations, vaccine storage, handling, security and assessment and management of adverse reactions, and
 - (iii) trained in the use of personal protective equipment (PPE) and wear the appropriate PPE for the setting in which they are working;

- (b) the engaged provider and any person involved in the administration of an RSV vaccine must have completed relevant CPD activity, through for example, regular educational updates, attendance at relevant courses provided by the Local Health Boards, as well as self-directed learning;
- (c) a clinical record of all vaccination related events must be entered onto the Welsh Immunisation System (WIS) in accordance with paragraph 4(6) of the relevant Directions.

5. Cluster working

Engaged providers are strongly encouraged to work collectively within professional collaborative or cluster groupings, whether or not these have previously been in place, and irrespective of which primary care services a provider usually provides, to maximise the level of vaccine delivery and uptake.

6. Patient Group Direction Template(s)

- (a) National Patient Group Direction template(s) will be developed to support service delivery. Engaged providers must ensure that they have access to and have considered all current versions of approved documents when providing services under this PCCS:I.
- (b) The engaged provider must ensure that vaccinations are administered only by a person permitted to do so in accordance with the Human Medicines Regulations 2012. All vaccines are classified as prescription only medicines (POMs). There needs to be an appropriate legal framework in place before they can be administered to eligible people. Any person who supplies and administers a vaccine must have a legal authority to do so. This legal authority may be in the form of a written patient specific prescription, a Patient Specific Direction (PSD), a Patient Group Direction (PGD) or another process such as a Protocol.
- (c) Engaged providers must have in place robust security measures to ensure the safety of patients, staff and the vaccines themselves.
- (d) All persons engaged in delivery of this PCCS:I must ensure that—
 - (i) there is a valid legal authority in place for vaccination of each patient;
 - (ii) they meet the requirements for characteristics of staff set out in the relevant legal authority;

- (iii) they have completed the required training, accreditation (where necessary) and competency assessment set out in the relevant legal authority;
- (iv) they have access to the relevant guidance and resources to undertake the vaccination;
- (v) a record is maintained of all persons authorised to administer vaccinations under this PCCS:I.

Those persons engaged in delivery of RSV vaccines under this PCCS:I will be covered by existing indemnity arrangements pursuant to regulation 8 of the National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019⁽¹⁾.

7. Vaccine Ordering, Storage and Wastage

- (a) Ordering will be via the Immform platform and not purchased by the provider. There will be separate ordering codes for the maternal and older adult programmes; orders should be placed accordingly by the engaged provider.
- (b) The engaged provider will be responsible for the provision of appropriate consumables required for the administration of vaccines under this Scheme.
- (c) All vaccines delivered under this PCCS:I will be free of charge to the eligible person receiving the vaccine. Private services for the provision of RSV vaccination to cohorts who are not eligible for NHS vaccination are excluded from this PCCS:I. Providers offering private services must not use NHS provided stock for private services.
- (d) Engaged providers must ensure that all vaccines are received, stored, prepared and subsequently transported (where appropriate) in accordance with the Public Health Wales and relevant manufacturer and Local Health Board guidance and all associated Standard Operating Procedures.
- (e) Appropriate procedures must be in place to ensure stock rotation, monitoring of expiry dates and appropriate use of vaccine stock to ensure that wastage is minimised. Wastage levels will be reviewed by the relevant Local Health Board and Vaccination Programme Wales on an ongoing basis. Any unusable supply should be logged by providers on Immform in line with local and national guidance.

(1) S.I. 2019/422 (W. 97).

- (f) All packaging relating to vaccines must be destroyed and defaced to prevent it being reused for any purpose. This includes the safe and secure disposal of empty vials via clinical waste to ensure they cannot be reused.

8. Accessibility and equality

- (a) Engaged providers must ensure that services are accessible, appropriate and sensitive to the needs of all persons.
- (b) No person eligible for vaccination by the engaged provider in accordance with this PCCS:I shall be excluded or experience particular difficulty in accessing and effectively using this PCCS:I 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.
- (c) Engaged providers undertaking this PCCS:I should work with their relevant Local Health Board to support the relevant Local Health Board's equality plans, in making vaccination as accessible as possible, including to those in under-served communities.

9. Record-keeping, surveillance and payments

The engaged provider must use the Welsh Immunisation System (WIS)—

- (a) for recording consent for vaccination,
- (b) for noting any contraindications,
- (c) for recording when a vaccination has been given, including the batch number and manufacturer expiry date,
- (d) if required, for supplying Public Health Wales with information on persons who have received a RSV vaccine, for the purpose of monitoring local and national uptake,
- (e) for recording immediate adverse events,
- (f) for recording the refrigerator temperature(s) where vaccines are stored, twice daily (at the start and end of the day) on all working days, as per national guidance,
- (g) for supplying NHS Wales Shared Services Partnership with information on persons who have received an RSV vaccine, for the purposes of payment and, if required, post payment verification, and
- (h) if required, for providing data to the collaborative or cluster lead practice (where

applicable), Local Health Boards, other NHS bodies and Welsh Government

The engaged provider must ensure consistent coding to enable the capture of data, and compliance with relevant information governance legislation.

10. Payment for administration of an RSV vaccine under this PCCS:I

The Local Health Board must pay to an engaged provider who qualifies for payment in accordance with paragraphs 5 and 6 of the relevant Directions a payment of—

- (a) the standard IoS fee, [currently £10.03] in respect of each dose of a RSV vaccine administered to a person under this PCCS:I;
- (b) from 1 September 2024 until 31 August 2025, in recognition of the additional administrative burden of updating the provider's own electronic systems alongside the requirement to update WIS, a top-up fee of £1.00 in respect of each dose of an RSV vaccine administered under this PCCS:I.

11. Adverse events

In addition to the requirement in paragraph 4(6)(c)(ii) of the relevant Directions to record on WIS, all adverse events relating to a vaccine **must** be reported to—

- (a) the MHRA using the [Yellow Card scheme\(1\)](#);
- (b) the Health Board (by using DATIX or the All Wales Concerns Management System, or existing local arrangements).

12. Co-administration

Guidance available in the Green Book chapter on RSV should be followed regarding co-administration of RSV vaccine with other vaccines. If recommendations suggest co-administration is appropriate, then this should be undertaken where possible to ensure efficient use of appointments and patient time.

13. Publicity and Promotion

- (a) The engaged provider will participate in any reasonable publicity and promotion of the service required by the Local Health Board. Publicity materials and information leaflets

(1) Abrysvo® is part of the Medicines and Healthcare products Regulatory Agency's (MHRA) Black Triangle Scheme for new medicines and vaccines to allow rapid identification of new safety information.

will be provided by the relevant Local Health Board or Public Health Wales.

- (b) Engaged providers should signpost information on how to access RSV vaccination within the health board area; for the maternal programme this may be within the practice if co-located with antenatal services, or at an alternative site as advised.

14. Notice Period

- (a) The notice period for ending the agreement for service provision under this Specification will be **90 days(1)**. Notice must be given in writing.
- (b) The arrangements between an engaged provider and a relevant Local Health Board for the provision of RSV vaccines pursuant to this PCCS:I and Specification may be terminated in any of the following events—
 - (i) automatically, in the event the RSV vaccination programme comes to an end,
 - (ii) the relevant Local Health Board requires that the engaged provider withdraws from the arrangement,
 - (iii) the relevant Local Health Board terminates the arrangement with the engaged provider by giving 90 days'(2) notice to the engaged provider,
 - (iv) the relevant Local Health Board terminates the arrangement by giving 90 days'(3) notice where the engaged provider has failed to comply with any reasonable request for information from that Local Health Board relating to the provision of the services under this PCCS:I, or
 - (v) the engaged provider cannot meet any of the requirements of this PCCS:I. Such notice must be received by the relevant Local Health Board 90 days(4) to the date on which the engaged provider wishes to withdraw its provision of services under this PCCS:I.

15. Application for Participation

Signature of engaged provider:

(1) Or a period agreed by both parties if less than 90 days.
(2) Or a period agreed by both parties if less than 90 days.
(3) Or a period agreed by both parties if less than 90 days.
(4) Or a period agreed by both parties if less than 90 days.

Date: