

**NWSI 2026 No. 18**

**NATIONAL HEALTH  
SERVICE, WALES**

**The Primary Care (Contracted  
Services: Immunisations) (RSV)  
(Wales) Directions 2026**

*Made* 3 February 2026

*Coming into force* 6 February 2026

The Welsh Ministers, in exercise of the powers conferred on them by sections 10, 12(3), 203(9) and (10), and 204(1)(b) of the National Health Service (Wales) Act 2006<sup>(1)</sup>, 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) (Wales) Directions 2026.

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

(3) These Directions come into force on 6 February 2026.

**Interpretation**

**2.** In these Directions—

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

“cluster” (“*chwstwr*”) 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 chwstwr*”) means a GMS contractor that has agreed to provide the Scheme to its registered patients,

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

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

“engaged provider” (“*darparwr sydd wedi ei gymryd ymlaen*”) means a GDS contractor, GMS contractor (whether acting for itself, as a cluster lead practice, or on behalf of another practice or group of practices), GOS contractor 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;

“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<sup>(1)</sup>;

“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<sup>(2)</sup> (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<sup>(3)</sup>, or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976<sup>(4)</sup>, or
- (b) lawfully carrying on a retail pharmacy business in accordance with section 69 of the Medicines Act 1968<sup>(5)</sup>;

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

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

(3) 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.

(4) 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 amended by regulation 2 of, and paragraph 13 of the Schedule to, S.I. 2019/585, and article 10 of S.I. 2022/849.

(5) 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

“NHS Wales Shared Services Partnership” (*Partneriaeth Cydwasaethau 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<sup>(1)</sup>;

“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<sup>(2)</sup>;

“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<sup>(3)</sup>;

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

- (a) a person who is recorded by the Local Health Board as being on a GMS contractor’s list of patients, or
- (b) a person whom the GMS contractor 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 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 cohort specified in paragraph 2 of the relevant specification;

“relevant specification” (*manyleb berthnasol*) means the specification contained in the 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;

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

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to, S.I. 2010/231; regulation 3 of, and paragraph 4 of Schedule 2 to, S.I. 2019/593.

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

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

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

### **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—

- (a) engaged providers, and
- (b) Local Health Boards (where there is an appropriate public health rationale, for example).

### **Primary Care Contracted Services: Immunisations Scheme for RSV**

4.—(1) Each Local Health Board may provide the services under the Scheme itself or may enter into arrangements for the provision of such services with—

- (a) GDS contractors,
- (b) 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 GMS contractors, 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 GMS contractor or group of GMS contractors, where that GMS contractor has agreed to deliver the Scheme pursuant to sub-paragraph (i), subject to the agreement of the other GMS contractor or group of GMS contractors,
- (c) GOS contractors, or
- (d) NHS pharmacists.

(2) Where the registered patients of a GMS contractor will not receive the services under the Scheme from GMS contractors under sub-paragraph (1)(b), the Local Health Board must make arrangements to ensure the provision of the services to the registered patients of that GMS contractor by providing the services itself or arranging for the delivery of those services by any other engaged provider.

(3) Where sub-paragraph (2) applies and 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 to the registered patients of the GMS contractor as close to the practice premises of that GMS contractor as is reasonably practicable.

(4) An arrangement made between a cluster lead practice and a Local Health Board in accordance with sub-paragraph (1)(b)(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 GMS contractors across the cluster.

(5) Sub-paragraph (4) applies whether a GMS contractor who is a member of the cluster is an engaged provider or not.

(6) For the purposes of sub-paragraph (4), where there is only one engaged provider, and it is the cluster lead practice, it is responsible for completing that plan.

(7) 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 provides the services under the Scheme in accordance 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 (4) 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, and

- (bb) 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,
  - (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 name of the person administering the vaccine,
    - (dd) the date and time the vaccine was administered,
    - (ee) where more than one vaccine is administered, the route of administration and the injection site of each dose of the vaccine,
    - (ff) any contraindications to the vaccine or immunisation,
    - (gg) any immediate adverse reactions to the vaccine or immunisation,
  - (iii) receipt of delivery of the vaccine on the day of its receipt,
  - (iv) the daily vaccine stock check balance on all working days before the end of each working day,
  - (v) 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,
  - (vi) 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,
- (vii) 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
  - (viii) 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 supply, storage and wastage requirements in paragraph 7 of the relevant specification and current guidance in chapter 3 (storage, distribution and disposal of vaccines) of the latest edition of the “Green Book”<sup>(1)</sup> 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 person involved in the provision of services under the Scheme has the necessary skills, training, competence and experience to provide those services;
  - (iii) ensures that each person 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 such person has undertaken the relevant training prior to participating in the administration of vaccinations;
  - (iv) ensures each person 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

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(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>

- knowledge and skills through their annual appraisal and revalidation;
- (v) ensures that each person involved in the provision of services under the Scheme is adequately 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 (4) or the engaged provider's performance in relation to the plan specified in sub-paragraph (7)(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 enable an engaged provider to claim in accordance with paragraph 10 of the relevant specification a payment of £10.03 per each dose of RSV vaccine administered.

(8) Where the Local Health Board delivers the Scheme itself in accordance with sub-paragraph (1) or (2), the Local Health Board must ensure that sub-paragraph (7) applies (as far as relevant in the circumstances).

### **Eligibility for and conditions of payment**

**5.—**(1) An engaged provider 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 whom 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) The Local Health Board may, in appropriate circumstances and in accordance with paragraph 7, 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) and an automatic payment will be made as follows—

- (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.

(4) In this paragraph—

“Drug Tariff” (“*Tariff Cyffuriau*”) has the meaning given to it in regulation 55 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020<sup>(1)</sup> (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors);

“Statement of Financial Entitlements” (“*Datganiad ar Hawlogaethau Ariannol*”) means any directions as to the Statement of Financial Entitlements 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.

### **Overpayments and withheld amounts**

7.—(1) 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

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

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.

(5) In this paragraph, “NHS services” 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.

### **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) the engaged provider has consented to later payment, 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<sup>(1)</sup> 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.

(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.

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

(7) The Welsh Ministers must give, with the written request 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 observations under sub-paragraph (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 they have 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 to the dispute.

(15) In this paragraph—

“specified period” means such period as the Welsh Ministers specify in a written request, being not less than 2, nor more than 4, weeks beginning with the date on which the written request referred to is made, 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.

## **General**

**12.** Nothing in these Directions authorises any administration of RSV vaccinations that would contravene the Human Medicines Regulations 2012<sup>(1)</sup>.

## **Revocation and saving provision**

**13.—**(1) The Primary Care (Contracted Services: Immunisations) (RSV) Directions 2024<sup>(2)</sup> are revoked.

(2) The Primary Care (Contracted Services: Immunisations) (RSV) Directions 2024 continue to apply in respect of any RSV vaccinations administered by an engaged provider in accordance with the Scheme established under those Directions immediately before the coming into force date of these Directions.

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(1) S.I. 2012/1916.

(2) WG 2024 No. 38.



*Jo Larner*

Deputy Director, Vaccination Policy, under the  
authority of the Cabinet Secretary for Health and  
Social Care, one of the Welsh Ministers  
3 February 2026



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 Cabinet Secretary for Health and Social Care agreed to the advice of the Joint Committee on Vaccination and Immunisation (JCVI) that a Respiratory Syncytial Virus (RSV) vaccination programme should be stood up to protect infants and individuals on reaching 75 years of age as they 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.

Guidance on RSV is available in chapter 27a of the Green Book.

**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.

Since the start of the PCCS:I RSV vaccination programme in 2024, its delivery has primarily been via GMS contractors and Local Health Board maternity settings. It is expected that the routine RSV vaccination programme (i.e. vaccination of individuals on reaching 75 years of age and the maternity programme) will continue to be delivered primarily by GMS contractors and maternity settings. However, a Local Health Board may wish to provide some services under the Scheme itself, for example, where there is an appropriate public health rationale to do so.

## **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 cohorts will be determined by the Welsh Government, based on the advice of the JCVI, and confirmed via a WHC from the Chief Medical Officer.

This specification only relates to those specific cohorts eligible and commissioned by the contracting Local Health Board. Vaccination outside of the specified eligible cohorts 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 programme—**

- (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) ensuring that those who are newly eligible are invited for vaccination within the time frame specified in the WHC, 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 relevant Local 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 relevant Local 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) (Wales) Directions 2026 (“the relevant Directions”), and this PCCS:I specification, after obtaining consent, and following guidance in the [Green Book](#) and relevant WHCs 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 cohorts eligible for vaccination under this specification and the sequence for delivery of the vaccination,
  - (iii) informed consent is obtained by the person who administers a vaccine,
  - (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) that consent obtained under 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) be 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(7) 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<sup>(1)</sup>.

## **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 programme and older adult programme; 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 relevant guidance of the manufacturer, Public Health Wales and Local Health Board, and all associated Standard Operating Procedures.

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<sup>(1)</sup> S.I. 2019/422 (W. 97).

- (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.
- (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 strategic equality plans, and any national or local planning to support vaccine equity, 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) for the following purposes and to record the following information, in particular, on the WIS—

- (a) any refusal of an offer of vaccination, or
- (b) where an offer of vaccination was accepted—
  - (i) 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),

- (ii) the batch number, expiry date and title of the vaccine,
- (iii) the name of the person administering the vaccine,
- (iv) the date and time the vaccine was administered,
- (v) where more than one vaccine is administered, the route of administration and the injection site of each dose of the vaccine,
- (vi) any contraindications to the vaccine or immunisation,
- (vii) any immediate adverse reactions to the vaccine or immunisation,
- (c) receipt of delivery of the vaccine on the day of its receipt,
- (d) the daily vaccine stock check balance on all working days before the end of each working day,
- (e) 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,
- (f) 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,
- (g) 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
- (h) to provide data to the cluster lead practice of a cluster (where applicable), Local Health Boards, other NHS bodies, and Welsh Government, when required.

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 the standard IoS fee, [currently £10.03] in respect of each dose of a RSV vaccine administered to a person under this PCCS:I.



## 11. Adverse events

In addition to the requirement in paragraph 4(7)(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 relevant Local 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 may 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(2)**. 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,

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(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.

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

- (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'(1) notice to the engaged provider,
- (iv) the relevant Local Health Board terminates the arrangement by giving 90 days'(2) 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(3) prior 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:

Date:

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(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.