
SUBORDINATE LEGISLATION

WG No. 21-70

**THE NATIONAL HEALTH SERVICE (WALES) ACT
2006**

**The Primary Care (Contracted Services: Immunisations)
Directions 2021**

Made

10 August 2021

Coming into force

18 August 2021

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⁾, make the following Directions.

Title, application and commencement

1.—(1) The title of these Directions is the Primary Care (Contracted Services: Immunisations) Directions 2021.

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

(3) These Directions come into force on 18 August 2021.

Interpretation

2. In these Directions—

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

“cluster” 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” means a general medical practitioner that has agreed to provide the Scheme to its 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” means a body corporate registered in the register of bodies corporate maintained under section 9 of the Opticians Act 1989⁽²⁾, which is carrying on business as an optometrist;

“Covid-19 vaccine” means [any vaccine authorised under the Human Medicines Regulations 2012 \(3\) for the vaccination or immunisation of individuals at risk from Covid-19;](#)

⁽¹⁾ 2006 c. 42.

⁽²⁾ 1989 c. 44.

⁽³⁾ [S.I. 2012/1916](#).

“Covid-19 Vaccines Specification” means the Primary Care Contracted Services: Immunisations (Covid-19 Vaccines) Specification at Schedule 1 to these Directions;

“dentist” means a dental practitioner—

- (a) who is registered in the dentists register, 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⁽¹⁾;

“dentists’ register” means the register referred to in section 14(1) of the Dentists Act 1984⁽²⁾;

“Drug Tariff” has the meaning given to it in regulation 55 of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020⁽³⁾ (the Drug Tariff and remuneration of NHS pharmacists and NHS appliance contractors);

“engaged provider” 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 pharmacist that agrees with a Local Health Board to provide services under the Scheme pursuant to an arrangement made in accordance with direction 4;

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

“general medical practitioner” 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⁽⁴⁾, 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” means a person who is a party to a contract with a Local Health Board under section 42 of the Act;

“GOS contractor” means a person who is included in a Local Health Board’s ophthalmic list and provides general ophthalmic services as part of the health service in Wales under the National Health Service (General Ophthalmic Services) Regulations 1986⁽⁵⁾;

“health care professional” 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⁽⁶⁾;

“Local Health Board” means a Local Health Board established in accordance with section 11(2) of the Act;

“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;

“optician” means a person who is—

- (a) registered in the register of optometrists maintained under section 7 (register of opticians) of the Opticians Act 1989 or in the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) of that Act, or
- (b) a corporate optician;

“pharmacist” means a person who is—

- (a) registered in Part 1 of the General Pharmaceutical Council Register⁽¹⁾ or in the register maintained under Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976⁽²⁾, or

(1) S.I. 2004/1020 (W. 117).

(2) 1984 c. 24, amended by S.I. 2005/2011 and S.I. 2007/3101.

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

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

(5) S.I. 1986/975.

(6) 2002 c. 17.

- (b) lawfully carrying on a retail pharmacy business in accordance with section 69 of the Medicines Act 1968⁽³⁾, and

whose name is included in a pharmaceutical list under regulation 10 (preparation and maintenance of pharmaceutical lists) of the National Health Service (Pharmaceutical Services) (Wales) Regulations 2020⁽⁴⁾, for the provision of pharmaceutical services in particular by the provision of drugs;

“registered patient” 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 notified by the Local Health Board as having ceased to be on that list;

“relevant specification” means any specification contained in a Schedule to these Directions;

“Scheme” means the Primary Care Contracted Services: Immunisations Scheme established by a Local Health Board in accordance with Direction 3;

“Statement of Financial Entitlements” 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” means any determination made by the Welsh Ministers pursuant to regulation 10 of the National Health Service (General Ophthalmic Services) Regulations 1986 in relation to payments to be made by a Local Health Board to a GOS contractor;

“Welsh Immunisation System” means the information system for the management, distribution and reporting of the COVID-19 Vaccination Programme.

Establishment of a Primary Care Contracted Services: Immunisations Scheme

3.—(1) Each Local Health Board must establish, operate and, as appropriate, revise a Primary Care Contracted Services: Immunisations Scheme.

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

Primary Care Contracted Services: Immunisations Scheme

4.—(1) As part of its Scheme, each Local Health Board may enter into arrangements for the provision of services in accordance with a relevant specification with—

- (a) a dentist;
- (b) a general medical practitioner—
 - (i) in relation to the registered patients of that general medical practitioner,
 - (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

(1) Maintained under article 19 (establishment, maintenance of and access to the Register) of the Pharmacy Order 2010 (S.I. 2010/231).

(2) S.I. 1976/1213 (N.I.22).

(3) 1968 c. 67.

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

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) and subject to the agreement of the other general medical practitioner or group of general medical practitioners;

(c) an optician; or

(d) a pharmacist.

(2) Where the registered patients of a general medical practitioner will not receive the services under the Scheme, whether from the general medical practitioner in relation to whom they are registered patients, from a cluster lead practice or a general medical practitioner who has agreed to deliver the Scheme on behalf of the general medical practitioner where the patient is registered, the Local Health Board must make arrangements to ensure the provision of the services to the registered patients of that general medical practitioner as close to the practice premises of that general medical practitioner as is reasonably practicable and the Local Health Board may deliver the services under the Scheme to those patients in any way it believes is appropriate (including, but not limited to, by providing the services itself or arranging for the delivery of those services by any engaged provider).

(3) An arrangement made between a cluster lead practice and a Local Health Board in accordance with 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 general medical practitioners across the cluster (whether or not a general medical practitioner is a member of the cluster is an engaged provider or not). Where there is only one engaged provider, and it is the cluster lead practice, it is responsible for completing that plan. Where there is no cluster lead practice, and all of the general medical practitioners in the cluster are engaged providers, they are all responsible for completing that plan.

(4) 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) reads and takes account of these Directions alongside complying with the relevant specification, which in combination provide the detailed requirements of the Scheme;

(ii) maintains and keeps up to date a record on the Welsh Immunisation System of all persons receiving treatment under the Scheme;

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

(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 vaccine but in any event no later than the end of the day on which a vaccine is administered, and in particular the engaged provider must record 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 2 vaccines are administered, the route of administration and the injection site of each dose of the vaccine,
 - (hh) any contraindications to the vaccination or immunisation, and
 - (ii) any adverse reactions to the vaccination or immunisation;
- (c) a requirement that the engaged provider—
 - (i) must adhere to the current guidance in chapter 3 (Storage, distribution and disposal of vaccines) of the latest edition of the “Green Book”(1),
 - (ii) has, as appropriate, the minimum necessary requirements for security specified in paragraphs 8(bb) to (ee) of the Covid-19 Vaccines Specification, and
 - (iii) adheres to all relevant conditions specified in the summary of product characteristics published by the manufacturers of each Covid-19 vaccine;
- (d) a requirement that the engaged provider—
 - (i) supplies 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;
 - (ii) supplies NHS Wales Shared Services Partnership, via the Welsh Immunisation System, with information on persons who have received a vaccine under the Scheme, for payment and post payment verification purposes;
 - (iii) provides data, subject to paragraph (vii) below, to the cluster lead practice of a cluster (where applicable), Local Health Boards and Welsh Government when required;
 - (iv) ensures consistent coding for capture of data and compliance with relevant information governance legislation;
 - (v) 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;
 - (vi) 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;
 - (vii) ensures each health care professional involved in the provision of services under the Scheme completes relevant CPD activity through, for example, regular educational updates, attendance at relevant courses provided by Local Health Boards, as well as

(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>

self-directed learning, to be able to demonstrate they have adequate knowledge and skills through their annual appraisal and revalidation;

- (viii) ensures that each health care professional involved in the provision of services under the Scheme is adequately indemnified/insured for any liability arising from the work performed;
 - (ix) 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 paragraph (3) or the engaged provider's performance in relation to the plan specified in paragraph (4)(iv);
 - (x) 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; and
 - (xi) completes an annual report of outcomes by 31 March each year;
- (e) payment arrangements for an engaged provider which must provide for it to be able to claim in accordance with paragraph 7 of the Covid-19 Vaccines Specification, a payment of—
- (i) £12.58 per Covid-19 vaccine administered, [and](#)
 - (ii) £400 per 1,000 Covid-19 vaccines administered.

(5) Where the Local Health Board delivers the Scheme pursuant to an arrangement in accordance with paragraph (2), the Local Health Board must ensure that paragraph (4) applies to such arrangements as it would to an engaged provider.

Eligibility for payment

5.—(1) A dentist, general medical practitioner, optician or 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 an engaged provider;
- (b) the person in respect of whom the payment for the administration of a Covid-19 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) all required details have been entered on to the Welsh Immunisation System to create a clinical record of immunisation with a vaccine for each person in respect of whom a payment is being claimed by the engaged provider;
- (d) the engaged provider does not receive any payment from any other source in respect of a vaccine (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 direction 8 (overpayments and withheld amounts); and
- (e) the engaged provider creates the clinical record on the Welsh Immunisation System prior to the end of the day on which a vaccine is administered.

Payment under the Scheme

6.—(1) 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, where applicable, for every 1,000 Covid-19 vaccines administered, 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 paragraph (1) falls due following the expiry of 14 days after the activity is captured under 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 GDS 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 pharmacist, on the next date when the pharmacist receives any other payments due under the Drug Tariff, and
- (e) in the case of any other engaged provider, no later than 8 weeks beginning with the date on which the engaged provider creates or updates the clinical record on the Welsh Immunisation System or as otherwise may be agreed between the Local Health Board and the engaged provider.

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

Conditions of payment

7.—(1) A payment under these Directions is only payable if an engaged provider satisfies the following conditions—

- (a) 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, where known, of the person, and
 - (iv) the date on which each dose of a [Covid-19](#) vaccine has been 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, withhold payment of any, or any part of, payments due under the Scheme if an engaged provider breaches any of these conditions.

Overpayments and withheld amounts

8.—(1) If 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,

the Local Health Board may recover the money paid 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, and where no such deduction can be made, it is a condition

of the payments made pursuant to the Scheme that the primary care provider must pay to the Local Health Board that equivalent amount.

(2) Where a Local Health Board is entitled pursuant to 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

9.—(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

10. Where a Local Health Board and the engaged provider agree (but the Local Health Board's agreement may be withdrawn where it is reasonable to do so and if it has given the engaged provider reasonable notice thereof), 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, direction 8 applies.

Post payment verification

11. Post payment verification(1) applies to the provision of services under the Scheme.

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

Dispute resolution

12.—(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 paragraphs (2) to (15) below.

(2) The procedure specified in the following 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 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 paragraph (2) must send the request under 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 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 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 receipt of any representations from the parties or, if earlier at the end of the period for making such representations specified in the request sent under paragraph (6) or (8), 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) pass to the person or persons so appointed any documents received from the parties under 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 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 paragraph (6), but only if they are made within the specified period;
- (b) any written observations made in response to a request under paragraph (8), but only if they are made within the specified period;
- (c) any oral representations made in response to an invitation under paragraph (10)(a);
- (d) the results of any consultation under paragraph (10)(b); and
- (e) any observations made in accordance with an opportunity given under paragraph (11).

(13) Subject to the other provisions within this direction 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 direction—

“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.

Revocations and savings

13.—(1) The following Directions are revoked, subject to paragraph (5).

(2) The Primary Care (Oxford/AstraZeneca Vaccine COVID-19 Immunisation Scheme) Directions 2020(1).

(3) The Primary Care (Moderna Vaccine COVID-19 Immunisation Scheme) Directions 2021(2).

(4) The Primary Care (Pfizer-BioNTech COVID-19 Immunisation Scheme) Directions 2021(3).

(5) The Directions specified in paragraph (2), (3) or (4) continue to apply in respect of those persons to whom an engaged provider administered a Covid-19 vaccine prior to 18 August 2021 in accordance with the relevant Primary Care Covid-19 Immunisation Scheme and for whom the engaged provider has not received a payment.

Signed by Alex Slade, Deputy Director, Primary Care Division, under the authority of the Minister for Health and Social Services, one of the Welsh Ministers



Dated: 10 August 2021

(1) WG No. 20-77.

(2) WG No. 21-32.

(3) WG No. 21-65.

SCHEDULE 1

Primary Care Contracted Services: Immunisations (Covid-19 Vaccines) Specification

1. Introduction

The long term response to the Covid-19 pandemic requires the deployment of a safe and effective vaccine with enough uptake in the ‘at risk’ and overall population to protect individual patients and reduce the burden on, and risk to, NHS services.

Rapid progress has been made with high levels of uptake across all age ranges. The vaccination programme continues to evolve and, as part of their planning, Local Health Boards have to consider a range of factors, including workforce, logistics and infrastructure. They also must take account of developments in the advice issued by the Joint Committee for Vaccination and Immunisation (“JCVI”) along with other guidance, as well as how best to meet the needs of their population.

Planning and the delivery of an evolving programme is therefore ongoing and has to respond to changes in the course of the pandemic, particularly with regard to those individuals eligible for a vaccine. This continues to be a whole NHS Wales approach with the strategic intent of immunising as many eligible individuals, as swiftly as possible, safely and with minimum waste.

Primary Care providers in Wales have an excellent track-record of delivering immunisation programmes, including the Covid-19 vaccine. They have the skilled and experienced workforce necessary to support the delivery of a mass vaccination programme.

As we move through the current and future phases of the vaccination programme, it is crucial that Local Health Boards remain flexible and enable primary care providers to continue to engage in vaccine delivery where that is needed, whilst also balancing this with ongoing delivery of essential services.

This Primary Care Contracted Services: Immunisations scheme (“PCCS:I”) Specification specifically relates to the delivery of [vaccines authorised under the Human Medicines Regulations for the vaccination or immunisation of individuals at risk from Covid-19](#) (which are together referred to in the Directions and this Specification as “the Covid-19 Vaccines”) by primary care providers, defined for the purpose of this specification as “engaged providers”.

2. Background

SARS-CoV-2 virus is the official name of the strain of coronavirus that causes the disease known as Covid-19. When a human is exposed to the SARS-CoV-2 virus, spike glycoprotein (S) found on the surface of the virus binds to ACE2 receptors on human cells to gain entry to the cells and cause an infection. Early vaccines act by boosting the ability of the body to recognise and develop an immune response to the spike protein, and this will help stop the SARS-CoV-2 virus from entering human cells and therefore prevent infection.

Vaccinating people against the SARS-CoV-2 virus is key to reducing the severe morbidity and mortality it causes, and providing a long term solution to controlling Covid-19. When safe and effective vaccines against Covid-19 are available it is essential that they are delivered quickly to those who need it.

Covid-19 vaccine supply to Wales is being managed centrally by the Welsh Government in conjunction with Local Health Boards. Engaged providers who participate in the PCCS:I will not be required to purchase any stock of a Covid-19 vaccine. All vaccines will be free and private supplies of vaccine will not be available.

A Patient Group Direction for administering Covid-19 vaccines has been authorised by each Local Health Board.

This is a consolidated version prepared by the Welsh Government to assist readers, it is not an official version of the Subordinate Legislation.

The Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020 (https://www.legislation.gov.uk/uksi/2020/1125/pdfs/uksi_20201125_en.pdf) also allow Covid-19 vaccines to be administered according to a two-step national protocol using registered, trained and competent health care professionals to carry out the clinical assessment, consent and preparation steps of delivery, whilst suitably trained, non-registered and competent members of staff will be able to administer a vaccine itself under clinical supervision by a registered health care professional. The Human Medicines Regulations do not specify who these non-registered vaccinators might be.

Clinical guidance for the Covid-19 vaccines, including the relevant national protocol for each vaccine, can be accessed via the following link;

- <https://gov.wales/clinical-guidance-coronavirus>

Those persons engaged in delivery of Covid-19 vaccines under this PCCS:I will be covered by existing indemnity arrangements pursuant to regulation 8 of the NHS (Clinical Negligence Scheme) (Wales) Regulations 2019.

3. Primary Care Contracted Services: Immunisations Scheme Aims

This PCCS:I provides a mechanism for primary care providers to enter into an arrangement with their Local Health Board (“the relevant Local Health Board”) to enable the provision of services to administer the Covid-19 vaccines as part of the health service in Wales and the wider Covid-19 vaccination programme led by Local Health Boards.

4. Cluster Working

Engaged providers are strongly encouraged to work collectively within cluster groupings, whether or not these have previously been in place and irrespective of which primary care services a provider usually provides, in order to maximise the level of vaccine delivery. For example, for a general medical practitioner this may mean administering vaccinations to people who are not registered with the provider administering the vaccine, whilst for other providers, it could also mean administering vaccines at venues away from their normal working location.

5. Eligible Cohorts and Individuals for Vaccination under the Primary Care Contracted Services: Immunisations Scheme

The JCVI advises UK health departments on immunisation and determines eligibility for each Covid-19 vaccine. Prioritisation amongst the eligible groups depends on vaccine characteristics and advice from the JCVI. This means that the use of each Covid-19 vaccine needs to be considered as part of the wider Covid-19 vaccination programme, where multiple vaccines and multiple models of delivery are in use.

All engaged providers should familiarise themselves with the current advice on eligible groups and individuals issued by the JCVI and/or the Chief Medical Officer to the Welsh Government, along with any guidance or Directions issued by the Welsh Ministers, prior to administering a Covid-19 vaccine to an eligible individual, specifically taking account of the vaccine type and dose required for the individual allocated to them by the relevant Local Health Board.

This PCCS:I Specification only relates to those specific groups and individuals eligible for a Covid-19 vaccine as determined by the relevant Local Health Board based on the JCVI and Welsh Government advice. Engaged providers who participate in this PCCS:I should ensure all of their staff are aware of who is eligible for vaccination under this Specification and the prioritised sequence for delivery.

All JCVI advice and guidance applicable to the Covid-19 vaccines programme, including the priority groups and the vaccination of eligible cohorts of individuals, can be accessed via;

- <https://www.gov.uk/government/collections/covid-19-vaccination-programme>.

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Welsh Government advice, guidance and directions applicable to the Covid-19 vaccines programme can be accessed via;

- <https://gov.wales/vaccine-coronavirus>, and
- <https://gov.wales/working-for-the-nhs-and-social-care-coronavirus>.

For full details of vaccination against Covid-19, health care practitioners should refer to the relevant chapters of the Green Book “Immunisation against infectious disease” at;

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

and MHRA authorisation documents at;

COVID-19 - GOV.UK (www.gov.uk)

6. Conditions for Service Delivery

In order for a primary care provider to be considered for participation in this PCCS:I, specifically to provide services administering Covid-19 vaccines in accordance with this Specification, all of the following conditions must be met—

- (a) There must be an up-to-date and appropriate level of equipment for **resuscitation and anaphylaxis**, specifically adrenaline, at any site where vaccination occurs.
- (b) All persons who are involved in administration of vaccinations must be—
 - (i) adequately **trained** in administration of multi-dose vaccinations, vaccine storage, handling, security and assessment and management of **resuscitation, anaphylaxis and aseptic no-touch techniques**, and
 - (ii) trained in the use of PPE, be supplied with and wear the appropriate PPE for the setting in which they are working.
- (c) All venues where vaccination occurs must have **been risk-assessed for transmission of coronavirus based on local guidance** and action taken to reduce risk where possible.
- (d) Patients, who for the purposes of this Specification are defined to mean a person who will be or has been administered a vaccine under this PCCS:I, should be advised in advance not to attend if feeling unwell. Nonetheless, some patients may present to the vaccination location unwell, or may become unwell whilst attending the vaccination location. Facilities must be in place for the assessment and management of patients who are unwell and this must include resources to manage fainting and anaphylaxis/cardiac arrest to a primary care level of skill. Reliance on 999 Paramedics is not appropriate. Engaged providers should consult the relevant protocol, advice and guidance to ensure that any observation and monitoring requirements for recipients of a Covid-19 vaccine are complied with.
- (e) The engaged provider and any person involved in the administration of a Covid-19 vaccine must have undertaken an appropriate training programme specific to the vaccine being used. Public Health Wales has provided an e-learning module: <https://www.e-lfh.org.uk/programmes/covid-19-vaccination/>
- (f) Engaged providers are encouraged to collaborate with other engaged providers within existing clusters but also, where necessary, to form new clusters specifically to deliver this PCCS:I, which can be with providers outside of their own profession, if they have not already done so.
- (g) A clinical record of immunisation with a Covid-19 vaccine must be entered onto the Welsh Immunisation System (“WIS”). Arrangements are being made at UK level with GP system providers for the WIS (and NHSE NIMS) to populate patient records automatically in order to avoid double entry.

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7. Payment for administration of a Covid-19 vaccine under this PCCS:I

- (a) The Local Health Board must pay to an engaged provider who qualifies for the payment in accordance with Directions 5 to 7, a payment of—
 - (i) £12.58 in respect of each dose of a Covid-19 vaccine administered to a person under this PCCS:I, and
 - (ii) £400 for every 1,000 vaccines administered under this PCCS:I.

8. PCCS:I Specification

Agreement of Eligible Cohorts

- (a) The relevant Local Health Board must develop a proactive and preventative approach to offering the Covid-19 vaccines by adopting robust call and reminder systems to contact individuals within eligible cohorts, with the aims of—
 - (i) maximising uptake in the interests of those persons, and
 - (ii) meeting any public health targets in respect of the administration of each Covid-19 vaccine.
- (b) The relevant Local Health Board must agree with the engaged provider that the engaged provider is to—
 - (i) participate in this PCCS:I to maximise the vaccination with the Covid-19 vaccines of specific cohorts of the population allocated to them by the relevant Local Health Board and in accordance with JCVI and/or the Chief Medical Officer to the Welsh Government, along with any guidance or Directions issued by the Welsh Ministers (see paragraph 5),
 - (ii) accept the order of the cohorts and timescale over which the vaccines will be administered, and
 - (iii) in the case of general medical practitioners, vaccinate eligible individuals who are not registered patients of their practice.

Publicity & Promotion

- (c) The engaged provider must **prominently display provided materials** advertising the availability of Covid-19 vaccinations for eligible groups. This should include displaying advertisements on the premises website, using social media as well as inside the premises.
- (d) **Booking** of appointments for vaccination must be booked via the WIS Core. Patients will be able to change their pre-booked appointment, should they need to, via the online booking system.

Model for Delivery

- (e) The engaged provider and relevant Local Health Board must agree the timing and location of vaccination clinic sessions in the plan agreed in accordance with Direction 4(4)(a)(iv).
- (f) The engaged provider is actively encouraged to **work collaboratively with other engaged providers** in a cluster to share resources and maximise efficiencies to deliver this PCCS:I.
- (g) The engaged provider is to notify the relevant Local Health Board of the number of vaccination slots they have available and of all vaccination clinic sessions start and finish times, and their locations, at least 14 days in advance.
- (h) Vaccination appointments and number of people per session must be agreed between the relevant Local Health Board and engaged provider.
- (i) The engaged provider may only administer the appropriate Covid-19 vaccine to those persons allocated to them by the relevant Local Health Board in accordance with the

Directions and this PCCS:I Specification, after obtaining consent, and following advice of the JCVI and/or the Chief Medical Officer to the Welsh Government, along with any guidance or directions issued by the Welsh Ministers and guidance in the Green Book.

- (j) The engaged provider must ensure that—
 - (i) all persons who receive vaccinations are eligible under a cohort and suitable clinically in accordance with law and guidance;
 - (ii) informed consent is obtained by a registered health care professional; and
 - (iii) the patient's consent to the vaccination (or the name of the person who gave consent to the vaccination and that person's relationship to the patient) must be recorded in accordance with law and guidance;
- (k) Consent obtained in accordance with sub-paragraph 8(j)(ii) must be recorded (as appropriate) for any necessary information sharing with the relevant Local Health Board, in accordance with data protection law and guidance;
- (l) Engaged providers must ensure a person receives the recommended vaccine as part of a course of vaccination, in order to comply with relevant JCVI and/or Chief Medical Officer to the Welsh Government's advice for each cohort;
- (m) Engaged providers must ensure that—
 - (i) the correct dosage of a Covid-19 vaccine is administered to each person as clinically appropriate and in accordance with the JCVI and/or Chief Medical Officer to the Welsh Government's advice;
 - (ii) they comply with relevant advice issued by the JCVI and/or the Chief Medical Officer to the Welsh Government, along with any guidance and Directions issued by the Welsh Ministers on, including but not limited to—
 - (aa) which Covid-19 vaccine is the most suitable for each cohort of people;
 - (bb) the relevant minimum interval post administration of a dose and/or infection with coronavirus (as applicable) is observed for administration of each vaccination;
 - (cc) the relevant vaccination time limitations and expiry date following reconstitution;
 - (dd) the number of doses and required dosage of each vaccine required to achieve the desired immune response for each patient; and
 - (ee) any other relevant guidance relating to the administration of the different types of vaccine and the different cohorts from time to time.

Persons involved in administering the vaccine

- (n) 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, as amended by the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, including under a relevant Patient Group Direction or under a National Protocol approved by the Welsh Ministers.
- (o) All health care professionals administering a Covid-19 vaccine, must have—
 - (i) read and understood the clinical guidance available at <http://nww.immunisation.wales.nhs.uk/covid-19-vaccination-programme>;
 - (ii) completed the additional online Covid-19 specific training modules available on the e-learning for health website when available. Engaged providers are to oversee and keep a record to confirm that all persons administering the vaccines have undertaken the training prior to participating in vaccinations;
 - (iii) the necessary experience, skills, training and competency to administer vaccines in general, including completion of the general immunisation training available on e-learning for health, and face-to-face administration training, where relevant;

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- (iv) the necessary experience, skills, training and competency to administer vaccines in general, including training with regard to the recognition and initial treatment of anaphylaxis; and
 - (v) ensured that registered health care professionals were involved in the preparation (in accordance with the manufacturer's instructions) of the vaccine(s) unless unregistered staff have been trained to do this.
- (p) All other persons administering a Covid-19 vaccine must—
 - (i) be authorised, listed, referred to or otherwise identified by reference to the Human Medicines (Coronavirus and Influenza) (Amendment) Regulations 2020, including under a relevant Patient Group Direction or National Protocol approved by Welsh Ministers;
 - (ii) while preparing and/or administering vaccinations be supervised by a health care professional fulfilling the requirements of sub-paragraph (o) above;
 - (iii) have completed the additional online Covid-19 specific training modules available on the e-learning for health website when available. Engaged providers must oversee and keep a record to confirm that all staff have undertaken the training prior to participating in administration of the vaccination. This includes any additional training associated with new Covid-19 vaccines that become available while this PCCS:I is in operation;
 - (iv) have the necessary skills and training to administer vaccines in general, including completion of the general immunisation training available on e-learning for health and face-to-face administration training, where relevant; and
 - (v) the necessary skills and training, including training with regard to the recognition and initial treatment of anaphylaxis.
- (q) Engaged providers must ensure that all Covid-19 vaccines are received, stored, prepared and subsequently transported (where appropriate) in accordance with the relevant manufacturer's, Public Health Wales and Local Health Board instructions and all associated Standard Operating Procedures, including that all refrigerators in which vaccines are stored have a temperature data logger installed inside the refrigerator which continuously monitors the temperature inside the refrigerator and can be downloaded by trained personnel to give a continuous temperature record for that refrigerator. Refrigerator temperature readings must be taken and recorded from the refrigerator temperature thermometer display on all working days and engaged providers must ensure that appropriate action is taken when readings are outside the recommended temperature.
- (r) Appropriate procedures must be in place to ensure stock rotation, monitoring of expiry dates and appropriate use of multi-dose vials to ensure that wastage is minimised and does not exceed 5% of the total number of vaccines supplied. Wastage levels will be reviewed by the relevant Local Health Board on an ongoing basis. Where wastage exceeds 5% of the vaccines supplied and that wastage is as a result of supply chain or relevant Local Health Board fault, those vaccines shall be removed from any wastage calculations when reviewed by the relevant LHB on an ongoing basis.
- (s) Engaged providers must ensure that services are accessible, appropriate and sensitive to the needs of all persons. No person allocated by a relevant Local Health Board is to be excluded or experience particular difficulty in accessing and effectively using this PCCS:I due to a protected characteristic under the Equality Act 2010, which includes Age, Disability, Gender Reassignment, Marriage and Civil Partnership, Pregnancy and Maternity, Race, Religion or Belief, Sex or Sexual Orientation.

Record-keeping

- (t) The engaged provider must use the **Welsh Immunisation System** to—
 - (i) record consent for vaccination,
 - (ii) note any contraindications,

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- (iii) record when a vaccination has been given, including the batch number and manufacturer expiry date,
- (iv) record immediate adverse events,
- (v) record the refrigerator temperature(s) where Covid-19 vaccines are stored, twice daily (start and end of the day) on all working days, as per Local Health Board guidance,
- (vi) record receipt of delivery of the vaccine on the day of receipt,
- (vii) record the daily vaccine stock check balance on all working days at the end of the last clinic session,
- (viii) provide evidence for payments under this PCCS:I, including for Post Payment Verification.
- (u) By using the Welsh Immunisation System, the record of vaccination of a person by the engaged provider will be sent electronically to the individual's GMS record.
- (v) The engaged provider must—
 - (i) supply Public Health Wales with information on persons who have received a Covid-19 vaccine, via the Welsh Immunisation System, for the purpose of monitoring local and national uptake;
 - (ii) supply NHS Wales Shared Services Partnership with information on persons who have received a Covid-19 vaccine, via the Welsh Immunisation System for the purposes of payment, and/or post payment verification;
 - (iii) provide data, to the cluster lead practice of a cluster (where applicable), Local Health Boards and Welsh Government when required; and
 - (iv) ensure consistent coding for capture of data and compliance with relevant information governance legislation.

Adverse Events

- (w) All adverse events relating to a Covid-19 vaccine must be reported to—
 - (i) the MHRA using the Yellow Card scheme www.yellowcard.gov.uk, and
 - (ii) the Health Board Primary Care Team (by using DATIX or the all Wales Concerns Management System, or existing local arrangements).
- (x) Studies are on-going regarding the co-administration of Covid-19 vaccines with the influenza vaccine. Where co-administration does occur, patients should be informed about the likely timing of potential adverse events relating to each vaccine. Engaged providers should refer to the available guidance which can currently be found [here](#).
- (y) The engaged provider must ensure the person receiving a Covid-19 vaccine has understood that failure to receive all recommended doses of a vaccine may render the vaccination ineffective and should ensure that a follow up appointment to receive the subsequent dose has been booked, acknowledging that in exceptional circumstances appointments may need to be moved, before administering the first dose of the vaccine.

Vaccine stock and consumables

- (z) The relevant Local Health Board must—
 - (i) coordinate vaccine supplies; and
 - (ii) provide consumables such as PPE, syringes and needles.

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Publicity and Information Materials

- (aa) Publicity materials and information leaflets are to be provided by the relevant Local Health Board.

Security

- (bb) The security assessment related to delivery of a Covid-19 vaccine is continually evolving. In order to ensure the safety of patients, staff and the vaccines themselves, engaged providers must have robust security measures in place.
- (cc) As a minimum this must include—
 - (i) lockable temperature controlled storage (vaccine fridge). This can include adaptation of an existing fridge;
 - (ii) lockable internal doors preventing access to vaccine storage by unauthorised persons;
 - (iii) lockable external windows and doors;
 - (iv) an operational intruder alarm, preferably linked to an Alarm Receiving Centre; and
 - (v) a robust and operational security process (including but not limited to premises locking up procedures, incident reporting procedures and ID checking) which all staff are aware of and are compliant with.
- (dd) All packaging relating to Covid-19 vaccines must be destroyed or defaced in such a manner that prevents them being reused for any purpose. This includes the safe and secure disposal of empty vials via the clinical waste stream to ensure they cannot be reused.
- (ee) Additional security measures that should also be considered and are desirable, include—
 - (i) operational external CCTV covering all entry points;
 - (ii) external lighting; and
 - (iii) operational internal CCTV covering the location of the vaccine storage.
- (ff) Due to the continually changing nature of the response to Covid-19 and the resources and vaccines that the NHS is able to deploy, these security arrangements must be responsive and may be frequently updated as necessary, dictated by any changes in the threat assessment. Engaged providers are expected to be alive to this issue and committed to providing the best possible delivery of this PCCS:I.

9. Termination of arrangements

- (gg) An arrangement between an engaged provider and a relevant Local Health Board for the provision of Covid-19 vaccines services made pursuant to these Directions and this PCCS:I Specification may be terminated—
 - (i) automatically, when the Covid-19 vaccination programme comes to an end;
 - (ii) immediately, where the relevant Local Health Board requires that the engaged provider withdraws from the arrangement because the relevant Local Health Board is of the opinion that the engaged provider is not complying with their obligations under this PCCS:I;
 - (iii) by the Local Health Board giving the engaged provider not less than 4 weeks' notice in writing, where the relevant Local Health Board wishes to terminate the arrangement with the engaged provider for any reason other than that specified by paragraph (ii); or
 - (iv) by the engaged provider giving the Local Health Board not less than 4 weeks' notice in writing, where the engaged provider wishes to terminate the arrangement with the relevant Local Health Board for any reason.

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10. Application for Participation

Signature of engaged provider

Date