
W E L S H S T A T U T O R Y
I N S T R U M E N T S

WG21-73**THE NATIONAL HEALTH
SERVICE (WALES) ACT 2006****The Primary Medical Services
(Influenza and Pneumococcal
Immunisation Scheme) (Directed
Enhanced Service) (Wales) (No. 2)
Directions 2021**

Made 31 August 2021

Coming into force 1 September 2021

The Welsh Ministers, in exercise of the powers conferred by sections 12(3), 45 and 203(9) and (10) of the National Health Service (Wales) Act 2006⁽¹⁾ and after consulting in accordance with section 45(4) of that Act with the bodies appearing to them to be representative of persons to whose remuneration these Directions relate, give the following Directions.

Title, commencement and application

1.—(1) The title of these Directions is the Primary Medical Services (Influenza and Pneumococcal Immunisation Scheme) (Directed Enhanced Service) (Wales) (No. 2) Directions 2021.

(2) These Directions come into force on 1 September 2021.

(3) These Directions have effect from 1 August 2021.

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

Interpretation

2. In these Directions—

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

(1) 2006 c. 42.

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

“cluster lead practice” (*“practis arweiniol y clwstwr”*) means a GMS contractor that has agreed to provide this Directed Enhanced Service to its registered patients, and to the registered patients of a GMS contractor in its cluster that is not an engaged GMS contractor, and which the Local Health Board agrees will be a cluster lead practice;

“engaged GMS contractor” (*“contractwr GMC sydd wedi ei gymryd ymlaen”*) means a GMS contractor that agrees with a Local Health Board to provide this Directed Enhanced Service pursuant to an arrangement made in accordance with Direction 4(1);

“financial year” (*“blwyddyn ariannol”*) means a year ending with 31 March;

“general practitioner” (*“ymarferydd cyffredinol”*) means a medical practitioner whose name is included in a medical performers list prepared by a Local Health Board under regulation 3 of the National Health Service (Performers Lists) (Wales) Regulations 2004(1);

“GMS contract” (*“contract GMC”*) means a general medical services contract entered into in accordance with section 42 of the Act;

“GMS contractor” (*“contractwr GMC”*) means a person with whom a Local Health Board is entering, or has entered, into a GMS contract;

“GMS Contracts Regulations” (*“Rheoliadau Contractau GMC”*) means the National Health Service (General Medical Service Contracts) (Wales) Regulations 2004(2);

“Green Book” (*“y Llyfr Gwyrdd”*) means the publication “Immunisation against infectious disease”(3);

“health care professional” (*“proffesiynolyn gofal iechyd”*) means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002(4);

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

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

(2) S.I. 2004/478 (W. 48).

(3) Available at:
<https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>

(4) 2002 c. 17.

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

- (a) a person who is recorded by the Local Health Board as being on the GMS contractor's list of patients, or
- (b) a person whom a 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;

“Statement of Financial Entitlements” (“*Datganiad ar Hawlogaethau Ariannol*”) means any directions given by the Welsh Ministers pursuant to section 45 of the Act in relation to payments to be made by a Local Health Board to a GMS contractor;

“young carer” (“*gofalwr ifanc*”) means a person who is aged under 25 and has a role in caring for another person.

Establishment of a General Practice Influenza and Pneumococcal Immunisation Scheme

3.—(1) Each Local Health Board is required under section 41 of the Act (primary medical services) to exercise its powers so as to provide, or secure the provision of, primary medical services within its area.

(2) As part of its discharge of its functions under section 41 of the Act, each Local Health Board must establish, operate and, where appropriate, revise a General Practice Influenza and Pneumococcal Immunisation Scheme.

(3) The underlying purpose of the General Practice Influenza and Pneumococcal Immunisation Scheme is to ensure that patients in each Local Health Board's area who are at risk of influenza or pneumococcal infection are offered immunisation against those infections⁽¹⁾.

General Practice Influenza and Pneumococcal Immunisation Scheme

4.—(1) As part of its General Practice Influenza and Pneumococcal Immunisation Scheme, each Local Health Board must offer to enter into arrangements with—

- (a) each GMS contractor, in relation to the registered patients of that GMS contractor; and then

(1) Further details about all the groups to be vaccinated can be found in the annual Chief Medical Officer's letter on the Seasonal Flu Immunisation Programme and the Green Book.

- (b) either—
- (i) one or more cluster lead practices, in relation to the registered patients of the cluster lead practice and the registered patients of those GMS contractors in its cluster, if any, that have not agreed within such time period as the Local Health Board requires, to deliver this Directed Enhanced Service pursuant to sub-paragraph (a), or
 - (ii) a GMS contractor that has agreed to deliver this Directed Enhanced Service pursuant to paragraph (a), and in relation to the registered patients of another GMS contractor or group of GMS contractors subject to the agreement of the other GMS contractor or group of GMS contractors.

(2) Where the patients of a GMS contractor will not receive the services outlined in this Directed Enhanced Service, whether from the GMS contractor in relation to whom they are registered patients, from a cluster lead practice or a GMS contractor who has agreed to deliver this Directed Enhanced Service on behalf of the GMS contractor where the patient is registered, the Local Health Board must make arrangements to ensure the provision of this Directed Enhanced Service to the registered patients of that GMS contractor as close to the practice premises of that GMS contractor as is reasonably possible and the Local Health Board may deliver the service under this Directed Enhanced Service 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 GMS contractor).

(3) Where arrangements are made between a cluster lead practice and a Local Health Board in accordance with paragraph (1)(b)(i), each engaged GMS contractor must co-operate⁽¹⁾ with the other engaged GMS contractors 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 this Directed Enhanced Service to registered patients of the GMS contractors across the cluster. Where there is only one engaged GMS contractor, 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 GMS contractors in the cluster are engaged GMS contractors, they are all responsible for completing that plan.

(1) See paragraph 12 of Part 1 of Schedule 6 to the GMS Contracts Regulations.

(4) Where arrangements are made between the Local Health Board and a GMS contractor pursuant to paragraph (1), those arrangements must, in respect of each financial year (or part of a year) to which they relate, include—

- (a) a requirement that the engaged GMS contractor completes to the satisfaction of the Local Health Board, prior to the provision of any services under this Directed Enhanced Service and by such date as the Local Health Board requires, a plan setting out the arrangements for the delivery of the services under the General Practice Influenza and Pneumococcal Immunisation Scheme by the engaged GMS contractor including, as a minimum—
 - (i) the dates and times when services under the Scheme will be delivered,
 - (ii) how the GMS contractor will continue to provide, without interruption, its essential services whilst it is an engaged GMS contractor, and
 - (iii) such other detail or assurances that the Local Health Board may reasonably request from the engaged GMS contractor;
- (b) a requirement that the engaged GMS contractor develops and maintains a register (its “Influenza and Pneumococcal Immunisation Scheme Register”, which may comprise electronically tagged entries in a wider computer database) of all the at-risk patients to whom the engaged GMS contractor is to offer immunisation against influenza or pneumococcal infection, and for these purposes a patient is at risk of—
 - (i) influenza infection, if the patient is—
 - (aa) aged 50 or over at the end of that financial year,
 - (bb) suffering from chronic respiratory disease (including asthma), chronic heart disease, chronic liver disease, chronic renal disease, chronic neurological disease, immuno-suppression due to disease or treatment, diabetes mellitus,
 - (cc) living in a long-stay residential or nursing home or other long stay health or social care facility,
 - (dd) an unpaid carer, including a young carer, of a person whose health or welfare may be at risk if the carer falls ill, including those who

receive a carer's allowance. The carer need not reside with, or be related to, the person being cared for. For this group it is at the engaged GMS contractor's discretion, in the context of other clinical risk groups on that contractor's list of patients, as to whether or not immunisation should be offered,

- (ee) a pregnant woman,
- (ff) a member of a recognised voluntary organisation who, as a member of that organisation, provides planned emergency first aid at organised public events,
- (gg) a Community First Responder⁽¹⁾,
- (hh) a locum doctor,
- (ii) suffering from a learning disability,
- (jj) morbidly obese and aged 18 or over at the end of that financial year,
- (kk) suffering from asplenia or dysfunction of the spleen,
- (ll) a person who works on a voluntary basis (not paid for their time and effort) providing care on a frequent basis to one, or more than one, elderly disabled or otherwise vulnerable person whose welfare would be at risk if the individual became ill,
- (mm) subject to agreement with the Local Health Board, a social care worker in regular contact with care home residents or domiciliary care workers, and
- (ii) pneumococcal infection, if the patient is aged 65 or over at the end of that financial year or is aged under 65 and is at risk of infection as defined in the latest edition of the Green Book;
- (c) a requirement that the engaged GMS contractor undertakes—
 - (i) to offer immunisations against influenza and pneumococcal infection to all at-risk patients; and

(1) Community First Responders providing direct emergency aid as part of a scheme operated by the Welsh Ambulance Service NHS Trust.

- (ii) for immunisations against influenza infection—
 - (aa) to make that offer during the period beginning with 1 August and ending with 31 March in that financial year and to concentrate the immunisation programme during the period beginning with 1 September and ending with 31 January in each financial year,
 - (bb) where influenza is still circulating at 31 March in any financial year, to continue to make that offer during the period beginning with 1 April and ending with 31 May of the following financial year, and
 - (cc) to provide an effective vaccine, taking into consideration the guidance issued in the annual Welsh Health Circular on vaccine ordering; and
- (iii) to record the information that it has offered the immunisations in accordance with paragraphs (i) and (ii), including whether that offer was accepted or refused, in its Influenza and Pneumococcal Immunisation Scheme Register using National Read codes;
- (d) a requirement that the engaged GMS contractor develops a proactive and preventative approach to offering influenza and pneumococcal immunisations by adopting robust call and reminder systems to contact at-risk patients, with the aims of—
 - (i) maximising uptake in the interests of at-risk patients, and
 - (ii) meeting any public health targets in respect of such immunisations;
- (e) a requirement that the engaged GMS contractor takes all reasonable steps to ensure that the lifelong medical records held by an at-risk patient's general practitioner are kept up to date with regard to their immunisation status and, in particular, to include—
 - (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 an at-risk patient's behalf, that person's relationship to the at-risk patient must also be recorded),

- (bb) the batch number, expiry date and title of the vaccine,
 - (cc) dose administered,
 - (dd) the date of the administration of the vaccine,
 - (ee) where 2 vaccines are administered, the route of administration and the injection site of each vaccine,
 - (ff) any contraindication to the vaccination or immunisation,
 - (gg) any adverse reaction to the vaccination or immunisation;
- (f) a requirement that the engaged GMS contractor ensures that any health care professional who is involved in administering a vaccine has—
- (i) the necessary experience, skills and training⁽¹⁾ with regard to the administration of that vaccine, and
 - (ii) training with regard to the recognition and initial treatment of anaphylaxis;
- (g) a requirement that the engaged GMS contractor ensures that it adheres to the current guidance in chapter 3 (Storage, distribution and disposal of vaccines) of the latest edition of the Green Book⁽²⁾;
- (h) a requirement that the engaged GMS contractor supplies Public Health Wales with information on patients, via automated data extraction, for the purposes of monitoring local and national uptake;
- (i) a requirement that the engaged GMS contractor—
- (i) ensures that each health care professional involved in the provision of this Directed Enhanced Service has the necessary skills, training, competence and experience in order to provide the services;
 - (ii) ensures each health care professional involved in the provision of this Directed Enhanced Service completes relevant CPD activity through, for example, regular educational updates, attendance at relevant courses provided by the Local

(1) Taking account of the National Minimum Standards and core curriculum for Immunisation Training at http://howis.wales.nhs.uk/sites3/page.cfm?orgid=474&pid=42421#National_Minimum_Standards_and_core_curriculum_for_Immunisation_Training.

(2) <https://www.gov.uk/government/publications/storage-distribution-and-disposal-of-vaccines-the-green-book-chapter-3>

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

- (iii) ensures that each health care professional involved in the provision of this Directed Enhanced Service considers any offer of educational update courses provided by the Local Health Board;
- (iv) ensures that each health care professional involved in the provision of this Directed Enhanced Service is adequately indemnified or insured for any liability arising from the work performed;
- (v) supplies its Local Health Board with such information as the Local Health Board may reasonably request for the purposes of monitoring the engaged GMS contractor's performance of its obligations under this Directed Enhanced Service in relation to the plan specified in paragraph (a) and, where applicable, the cluster's performance in relation to the plan specified in paragraph (3);
- (j) payment arrangements for an engaged GMS contractor, which must provide for it to be able to claim (whether acting just for itself, on behalf of another GMS contractor or as a cluster lead practice)—
 - (i) a payment of £10.03 per vaccine administered, and
 - (ii) the payment specified in paragraph (i) where, at the request of the Local Health Board, the engaged GMS contractor has administered a vaccine to staff working in adult residential care homes, nursing homes and children's hospices or to a person providing domiciliary care,

and after the payments are due, as above, and authorised by the Local Health Board, such payments will then be paid on the date the engaged GMS contractor's Global Sum monthly payment next falls due in accordance with the Statement of Financial Entitlements.

(5) The Local Health Board must, where necessary, vary the engaged GMS contractor's GMS contract so that the arrangements made pursuant to paragraph (1) comprise part of that engaged GMS contractor's contract and the requirements of the arrangements are conditions of the contract.

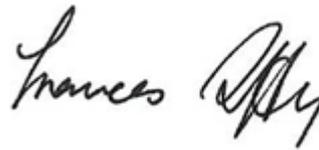
(6) Any disputes arising as a result of provision of this Directed Enhanced Service will be dealt with in

accordance with Part 7 of Schedule 6 to the GMS Contracts Regulations.

(7) Where the Local Health Board delivers this Directed Enhanced Service pursuant to an arrangement in accordance with paragraph (2), the Local Health Board must ensure that paragraphs (4) and (5) apply to such arrangements as they would to an engaged GMS contractor.

Revocations

5.—(1) The Primary Medical Services (Influenza and Pneumococcal Immunisation Scheme) (Directed Enhanced Service) (Wales) Directions 2021(1) are revoked.

A handwritten signature in black ink, appearing to read 'Frances Duffy', is positioned above the typed name and title.

Signed by Frances Duffy, Director, Primary Care and Health Science under the authority of the Minister for Health and Social Services, one of the Welsh Ministers

Dated: 31 August 2021