S U B O R D I N A T E L E G I S L A T I O N

2020 No. WG20-70

THE NATIONAL HEALTH SERVICE (WALES) ACT 2006

The Primary Medical Services
(General Practice Seasonal
Influenza Additional Immunisation
Scheme) (Directed Enhanced
Service) (Wales) Directions 2020

Made 2 December 2020

Coming into force 2 December 2020

The Welsh Ministers give the following directions 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.

Title, commencement and application

- **1.**—(1) The title of these Directions is the Primary Medical Services (General Practice Seasonal Influenza Additional Immunisation Scheme) (Directed Enhanced Service) (Wales) Directions 2020.
 - (2) These Directions—
 - (a) come into force on 2 December 2020,
 - (b) have effect from 1 December 2020, and
 - (c) expire on 1 June 2021.
- (3) 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;

"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 eligible patients, and to the eligible 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;

"eligible patient" ("claf cymwys") means a registered patient who, on 31 March 2021, is at least 50 years of age but less than 65 years of age;

"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 medical services contract" ("contract gwasanaethau meddygol cyffredinol") means a contract for general medical services between a GMS contractor and a Local Health Board made pursuant to 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 general medical services contract;

"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(1);

"Local Health Board" ("Bwrdd Iechyd Lleol") means a Local Health Board established under section 11 of the Act (local health boards);

"registered patient" ("claf cofrestredig") has the meaning given to it in regulation 2(1) of the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(2);

"Statement of Financial Entitlements" ("Datganiad ar Hawlogaethau Ariannol") means any directions given by the Welsh Ministers pursuant to section

^{(1) 2002} c. 17.

⁽²⁾ S.I. 2004/478 (W. 48).

45 of the Act in relation to payments to be made by a Local Health Board to a GMS contractor.

Establishment of a General Practice Seasonal Influenza Additional Immunisation Scheme

- **3.**—(1) Each Local Health Board is required under section 41 of the Act (primary medical services) to exercise its functions 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, as appropriate, revise a General Practice Seasonal Influenza Additional Immunisation Scheme
- (3) The underlying purpose of the General Practice Seasonal Influenza Additional Immunisation Scheme is to enable the provision of influenza vaccines by GMS contractors to persons who are aged at least 50 but less than 65 years of age during financial year 2020/2021.

General Practice Seasonal Influenza Additional Immunisation Scheme

- **4.**—(1) As part of its General Practice Seasonal Influenza Additional Immunisation Scheme, each Local Health Board must offer to enter into arrangements with—
 - (a) each GMS contractor, in relation to the eligible patients of that GMS contractor; and then
 - (b) either—
 - (i) one or more cluster lead practices, in relation to the eligible patients of the cluster lead practice and the eligible patients of those GMS contractors, if any, in it's cluster that have not agreed, within such time period as the Local Health Board requires, to deliver this Directed Enhanced Service to their eligible patients pursuant to sub-paragraph (a), or
 - (ii) a GMS contractor that has agreed to deliver this Directed Enhanced Service pursuant to paragraph (a) in relation to the eligible 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 eligible patients of a GMS contractor will not receive the services outlined in this Directed Enhanced Service, either from the GMS contractor in relation to whom they are registered patients, or from a cluster lead practice, the Local Health Board must

make arrangements to ensure the provision of these services to the eligible patients of that GMS contractor as close to the practice premises of that GMS contractor as is reasonably practicable and the Local Health Board may deliver the services 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 eligible patients of the engaged GMS contractors across the cluster. Where there is only one engaged GMS contractor, and it is the cluster lead practice, it shall be 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 shall all be responsible for completing that plan.
- (4) Where arrangements are made between the Local Health Board and a GMS contractor pursuant to paragraph (1), those arrangements must, in respect of financial year 2020/2021 (or part of that financial year), include—
 - (a) a requirement that the GMS contractor develops and maintains a register (its "Influenza Additional Immunisation Scheme Register", which may comprise electronically tagged entries in a wider computer database) of all eligible patients to whom the GMS contractor is to offer immunisation against influenza infection;
 - (b) a requirement that the GMS contractor undertakes—
 - (i) to offer immunisations against influenza infection to all eligible patients—
 - (aa) to make that offer during the period beginning with 1 December and ending with 31 March in that financial year and to concentrate the immunisation programme during the period beginning with 1 December and ending with 31 January in that financial year,

⁽¹⁾ See paragraph 12 of Part 1 of Schedule 6 to the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004 (S.I. 2004/478 (W.48)).

- (bb) where influenza is still circulating at 31 March, to continue to make that offer during the period beginning with 1 April and ending with 31 May, and
- (cc) to provide the vaccine specified in Public Health Link CEM/CMO/2020/27(1) or, where available, a vaccine from a GMS contractor's existing stock and which was not centrally supplied in accordance with Public Health Link reference CEM/CMO/2020/25(2), and
- (ii) to record the information that it has in its Influenza Additional Immunisation Scheme Register using National Read codes;
- (c) a requirement that the GMS contractor develops a proactive and preventative approach to offering these immunisations by adopting robust call and reminder systems to contact eligible patients who are, or will be on the last day of financial year 2020/21, at least 50 years of age but less than 65 years of age, with the aims of—
 - (i) maximising uptake in the interests of those patients, and
 - (ii) meeting any public health targets in respect of such immunisations;
- (d) a requirement that the GMS contractor takes all reasonable steps to ensure that the lifelong medical records held by an eligible patient's general practitioner are kept up-to-date with regard to that patient's immunisation status, and in particular to include—
 - (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 a patient's behalf, that person's

(1) Issued on 25 November 2020 and available via the following link:

http://www2.nphs.wales.nhs.uk:8080/Contacts.nsf/Main%20 Framset?OpenFrameSet&Frame=Right&Src=%2FContacts. nsf%2FEmailPublicView%2F50e2471c15cabbb18025862b0 05a4907%3FOpenDocument%26AutoFramed

(2) Issued on 25 November 2020 and available via the following link:

http://www2.nphs.wales.nhs.uk:8080/Contacts.nsf/Main%20 Framset?OpenFrameSet&Frame=Right&Src=%2FContacts. nsf%2FEmailPublicView%2F50e2471c15cabbb18025862b0 05a4907%3FOpenDocument%26AutoFramed

- relationship to the 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 contraindications to the vaccination or immunisation,
- (gg) any adverse reactions to the vaccination or immunisation;
- (e) a requirement that the GMS contractor ensures that any health care professional who is involved in administering a vaccine has—
 - (i) any necessary experience, skills and training(1) with regard to the administration of the vaccine, and
 - (ii) training with regard to the recognition and initial treatment of anaphylaxis;
- (f) a requirement that the GMS contractor ensures that it adheres to the current guidance on "Storage, distribution and disposal of vaccines" in the latest edition of the "Green Book"(2);
- (g) a requirement that the GMS contractor supplies its Local Health Board with such information as it may reasonably request for the purposes of monitoring the GMS contractor's performance of its obligations under the plan;
- (h) a requirement that the GMS contractor supplies Public Health Wales with information on eligible patients, via automated data extraction, for the purpose of monitoring local and national uptake;
- (i) a requirement that the GMS contractor—
 - (i) ensures that each health care professional undertaking this Directed Enhanced Service has the necessary skills, training, competence and experience in order to provide the services;

(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) "Green Book" means 'Immunisation against infectious disease' at http://immunisation.dh.gov.uk/category/the-green-book/

- (ii) ensures each health care professional undertaking this Directed Enhanced Service completes 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, to be able to demonstrate they have adequate knowledge and skills through their annual appraisal and revalidation;
- (iii) ensures that each health care professional undertaking this Directed Enhanced Service considers any offer of educational update courses provided by the Local Health Board;
- (iv) ensures that each health care professional undertaking this Directed Enhanced Service is adequately indemnified / 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, and the cluster's performance in relation to the plan specified in paragraph (3) above;
- (j) payment arrangements for an engaged GMS contractor, which must provide for it to be able to claim (whether acting just for itself or as a cluster lead practice)—
 - (i) a payment of £13.78 per vaccine administered during the period beginning with 1 December 2020 and ending with 31 March 2021 or, in the event that subparagraph (b)(i)(bb) applies, 31 May 2021, where the GMS contractor has administered a vaccine supplied in accordance with Public Health Link references CEM/CMO/2020/25 and CEM/CMO/2020/27,
 - (ii) a payment of £11.78 per vaccine administered during the period beginning with 1 December 2020 and ending with 31 March 2021 or, in the event that subparagraph (b)(i)(bb) applies, 31 May 2021, where the GMS contractor has administered a vaccine from existing stock available to that GMS contractor and which was not centrally supplied in accordance with Public Health Link reference CEM/CMO/2020/25, and

(iii) the payment specified in paragraph (i) where, at the request of the Local Health Board, the 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 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 GMS contractor's general medical services contract so that the arrangements made pursuant to paragraph (1) comprise part of the 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 National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(1).
- (7) Where the Local Health Board delivers this Directed Enhanced Service pursuant to an arrangement in accordance with paragraph (2), the Local Health Board shall ensure that paragraphs (4) and (5) apply to such arrangements as they would to an engaged GMS contractor.

Stade

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: 2 December 2020