

2016 No. 13 (W.13)

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

The Primary Medical Services
(Pertussis Immunisation for
Pregnant and Post-natal Women)
(Directed Enhanced Services)
(Wales) Directions 2016

Made 16 June 2016

Coming into force 17 June 2016

The Welsh Ministers, in exercise of the powers conferred by sections 12(3), 203(9) and (10) and 204(1) of the National Health Service (Wales) Act 2006⁽¹⁾ give the following Directions:

Title, commencement and application

1.—(1) The title of these Directions is the Primary Medical Services (Pertussis Immunisation for Pregnant and Post-natal Women) (Directed Enhanced Services) (Wales) Directions 2016.

(2) These Directions come into force on 17 June 2016.

(3) These Directions are given to Local Health Boards⁽²⁾ and apply in relation to Wales.

Interpretation

2. In these Directions—

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

“financial year” (“*blwyddyn ariannol*”) means the period from 1 April to 31 March;

(1) 2006 c. 42.

(2) Local Health Boards established pursuant to section 11 of the National Health Service (Wales) Act 2006.

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

“healthcare professional” (“*gweithiwr gofal iechyd proffesiynol*”) 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(2);

“PMS contractor” (“*contractwr PMS*”) means a person with whom a Local Health Board is entering or has entered into arrangements in accordance with section 50 of the Act which require the provision by that person of primary medical services;

“primary medical services contractor” (“*contractwr gwasanaethau meddygol sylfaenol*”) means—

- (a) a GMS or PMS contractor, or
- (b) a person with whom a Local Health Board is making or has made contractual arrangements for the provision of primary medical services under section 41(2)(b) of the Act; and

“Statement of Financial Entitlement” (“*Datganiad ar Hawlogaeth Ariannol*”) means any directions given by the Welsh Ministers under section 45 of the Act.

Establishment of a Pertussis Immunisation for Pregnant and Post-natal Women Scheme

3. Each Local Health Board must exercise its functions under section 41 of the Act of providing primary medical services within its area, or securing the provision of such services within its area, by (as part of its discharge of those functions) establishing (if it has not already done so), operating and, as appropriate, revising a Pertussis Immunisation for Pregnant and Post-natal Women Scheme, the underlying purpose of which is to extend the temporary programme of pertussis vaccination of pregnant and post-natal women in response to ongoing increased levels of pertussis activity.

(1) S.I. 2004/1020 (W. 117) as amended.
(2) 2002 c. 17.

Pertussis Immunisation for Pregnant and Post-natal Women Scheme

4.—(1) As part of its Pertussis Immunisation for Pregnant and Post-natal Women Scheme, each Local Health Board may enter into arrangements with each primary medical services contractor (“the contractor”) in its area (unless it already has such arrangements with the contractor in respect of that financial year), thereby affording the contractor a reasonable opportunity to participate in the Scheme during that financial year.

(2) The plan setting out the arrangements that a Local Health Board enters into, or has entered into, with the contractor must, in respect of each financial year to which the plan relates include—

- (a) a requirement that the contractor develop and maintains a register (“the Pertussis Immunisation for Pregnant and Post-natal Women Scheme Register”), of all the at-risk patients to whom the contractor is to offer pertussis immunisations. The Pertussis Immunisation for Pregnant and Post-natal Women Scheme Register may comprise electronically tagged entries in a wider computer database. For these purposes a patient is at-risk of pertussis infection if she is—
 - (i) a pregnant woman from 16 weeks onwards, with the optimal time in the period of weeks 16 to 32 inclusive, and with a gap of at least one month between any previous immunisation against pertussis, diphtheria, tetanus and/or polio, and this dose;
 - (ii) a pregnant woman from 32 weeks until the onset of labour, if immunisation was not given during the optimal time period set out in paragraph (i); or
 - (iii) a new mother who was not vaccinated against pertussis during her pregnancy and whose child has not received their first vaccinations;
- (b) a requirement that the contractor undertakes, when they are aware that their patient is pregnant—
 - (i) to offer immunisation to those patients;
 - (ii) to record the information it has in its the Pertussis Immunisation for Pregnant and Post-natal Women Scheme Register using the applicable National Read codes; and
 - (iii) to develop a proactive and preventative approach to offering the pertussis

- immunisation by adopting robust call and reminder systems with the aims of—
- (aa) maximising uptake in the interest of at risk patients; and
 - (bb) meeting any public health targets in respect of such immunisations;
- (c) a requirement that the 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 her immunisation status, and in particular 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 (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) the date of administration of the vaccine;
 - (dd) where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;
 - (ee) any contraindications to the vaccination; and
 - (ff) any adverse reactions to the vaccination;
- (d) a requirement that the contractor ensures that any healthcare professional who is involved in administering a vaccine has—
- (i) any necessary experience, skills and training with regards to the administration of the vaccine with reference to national minimum standards; and
 - (ii) training with regard to the recognition and initial treatment of anaphylaxis;
- (e) a requirement that the contractor ensures that—
- (i) all vaccines are stored in accordance with the manufacturer's instructions;
 - (ii) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that readings are taken from that thermometer on all working days; and

(iii) all vaccines are ordered, stored and monitored to reduce wastage;

(f) a requirement that the contractor supply its Local Health Board with such information and at such frequencies as the Local Health Board may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the plan; and

(g) the payment arrangements for the contractor.

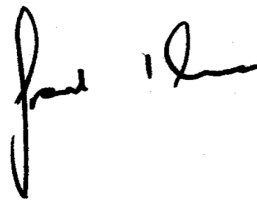
(3) The payment arrangements must provide that—

(a) where the contractor and Local Health Board have agreed arrangements as outlined in subparagraphs (a) to (g) and the contractor meets its obligations under the plan, the contractor will be able to claim (after verification by the Local Health Board) a payment of £7.80 per registered patient; and

(b) such payment will be payable quarterly in arrears and will be payable on the first date after the payment is authorised on which one of the contractor's Global Sum monthly payments falls due in accordance with the Statement of Financial Entitlement.

(4) Any disputes arising will be dealt with in the prescribed way. Local Health Boards and contractors should make every effort to resolve the dispute locally before formally submitting it through the NHS dispute resolution procedure.

(5) The Local Health Board must, where necessary, vary the contractor's general medical services contract so that the plan comprises part of the contractor's contract and the requirements of the plan are conditions of the contract.



Dr Grant L. Duncan

Signed by Dr Grant L. Duncan, Deputy Director,
Primary Care Division under the authority of the
Cabinet Secretary for Health, Well-being and Sport,
one of the Welsh Ministers

Date 16 June 2016