

THE HEALTH AND SOCIAL (REFORM) ACT (NORTHERN IRELAND) 2009

The Primary Medical Services (Directed Enhanced Services - Pandemic Influenza (H1N1) Vaccination Scheme) and Statement of Financial Entitlements (Amendment) Directions (Northern Ireland) 2009

The Department of Health, Social Services and Public Safety(a), having consulted in accordance with Article 57C (4) of the Health and Personal Social Services (Northern Ireland) Order 1972 (b)and section 6(2) of the Health and Social Care (Reform) Act (Northern Ireland) 2009(c), and in exercise of the powers conferred on it by Article 57C of the Health and Personal Social Services (Northern Ireland) Order 1972 and section 6 of the Health and Social Care (Reform) Act (Northern Ireland) 2009 hereby gives the following Directions—

Citation, commencement and application

1.—(1) These Directions may be cited as the Primary Medical Services (Directed Enhanced Services) Pandemic Influenza (H1N1) Vaccination Scheme) and Statement of Financial Entitlements (Amendment) Directions (Northern Ireland) 2009.

(2) These Directions are given to the Regional Health and Social Care Board and shall come into operation on 6th November 2009.

Interpretation

2. In these Directions—

“appropriate dosage” means the recommended doses of the H1N1 vaccine as specified in the vaccine schedule in the letter signed by the Chief Medical Officer, the Chief Medical Nursing Officer, the Chief Pharmaceutical Officer dated 15 October 2009 and published on the website of the Department of Health, Social Services and Public Safety(d);

“the Department” means the Department of Health, Social Services and Public Safety;

“the Regional Board” means the Regional Health and Social Care Board established under section 7 of the Health and Social Care (Reform) Act (Northern Ireland) 2009;

“the Order” means the Health and Personal Social Services (Northern Ireland) Order 1972;

“contractor” means a person who on or before the 6th November 2009 has entered into a general medical services contract with the Regional Board;

“H1N1 vaccine” means the Pandemic Influenza Vaccine (H1N1) 2009;

“priority group” is to be construed in accordance with direction 4;

(a) See S.I. 1999/283 (N.I. 1) Article 3(6)

(b) S.I. 1972/1265 (N.I. 14) relevant amending instrument is S.I. 2004/311 (N.I. 2)

(c) 2009 c.1

(d) A copy of the letter may be downloaded from the website at <http://www.dhsspsni.gov.uk/hss-md-44-2009.pdf>

“registered patient list” is to be construed in accordance with regulation 2(2) of the (Primary Medical Services (Sale of Goodwill and Restrictions on Sub-contracting) Regulations (Northern Ireland) 2004(a);

“SFE” means the Directions given by the Department in the Statement of Financial Entitlements under Article 57C of the 1972 Order

and

“working day” has the same meaning as in the Health and Personal Social Service (General Medical Services Contracts) Regulations (Northern Ireland) 2004(b).

PART 1

Establishment etc. of Pandemic Influenza (H1N1) Vaccination Schemes

3. The Regional Board must exercise its functions under Article 56 of the Order of providing primary medical services, or securing their provision, by (as part of its discharge of those functions) establishing, operating and, as appropriate, revising a Pandemic Influenza (H1N1) Vaccination Scheme, the underlying purposes of which are—

- (a) to ensure that patients in its area who are in a priority group are offered the H1N1 vaccine;
- (b) to ensure that the priority groups are prioritised for vaccination in the order set out in direction 4; and
- (c) to maximize the level of uptake amongst priority groups in its area of the H1N1 vaccine.

Priority groups

4. The following groups are priority groups for the purposes of these Directions—

- (a) people who—
 - (i) have reached the age of 6 months but have not reached the age of 65 years; and
 - (ii) are in a clinical risk group listed in the Schedule to these Directions;
- (b) women who—
 - (i) are pregnant; and
 - (ii) are at a stage in their pregnancy for which the H1N1 vaccine is licensed for use;
- (c) people who are household contacts of immunocompromised individuals; and
- (d) people who—
 - (i) are aged 65 or over; and
 - (ii) are in a clinical risk group listed in the Schedule to these Directions.

Offers of arrangements to participate in the Pandemic Influenza (H1N1) Vaccination Scheme

5.—(1) As part of its Pandemic Influenza (H1N1) Vaccination Scheme, the Regional Board must, subject to paragraph (2), offer to make arrangements with contractors for the vaccination of patients in priority groups against pandemic influenza of the virus sub-type H1N1.

(2) The Regional Board must—

- (i) before 20th November 2009, offer each contractor the opportunity to enter into arrangements to participate in the Pandemic Influenza (H1N1) Vaccination Scheme; and

(a) S.R. 2004 No. 477

(b) S.R. 2004 No. 140

- (ii) afford each of those contractors a reasonable opportunity to participate in the Pandemic Influenza (H1N1) Vaccination Scheme,
 - but for these purposes, if a contractor fails to respond to an offer within 14 days of the date on which the offer is made by the Regional Board, that contractor is to be treated as having been afforded a reasonable opportunity to participate in the Pandemic Influenza (H1N1) Vaccination Scheme and the offer may be withdrawn;
- (b) before entering into arrangements with contractors, satisfy itself that the contractor—
 - (i) is capable of meeting its obligations under those arrangements; and
 - (ii) in particular, has the necessary facilities, equipment and suitably trained and qualified general practitioners, health care professionals and staff to meet those obligations,

and nothing in these Directions shall be taken as requiring the Regional Board to enter into arrangements with a contractor if it is not so satisfied.
- (3) The Regional Board may withdraw an offer to enter into arrangements with a contractor as part of its Pandemic Influenza (H1N1) Vaccination Scheme if the contractor fails to provide any information—
 - (a) requested by the Regional Board which it reasonably requires in order to satisfy itself as mentioned in paragraph (2)(b); and
 - (b) within a timescale reasonably requested by the Regional Board.

Form and content of the arrangements

6.—(1) The arrangements that the Regional Board, as part of its Pandemic Influenza (H1N1) Vaccination Scheme, enters into with contractors must be contractual arrangements, in writing, which include the following—

- (a) a list (the “housebound patients list”) of those of the contractor’s registered patients who are in a priority group but who are housebound (that is, they are a patient to whom the contractor would normally offer home visits as the only practical means of enabling the patient to consult a general practitioner, face to face), and a provision to the effect that—
 - (i) the contractor is not under an obligation to offer a patient on the housebound patients list the H1N1 vaccine; and
 - (ii) the Regional Board shall not recover the cost of administering the H1N1 vaccine to those patients on the housebound patients list from the contractor;
- (b) the arrangements under which the Regional Board will supply H1N1 vaccine to the contractor;
- (c) a requirement to provide the Regional Board with such information relation to the contractor’s arrangements for administering the H1N1 vaccine that the Regional Board requires for the purposes of co-ordinating the supply of H1N1 vaccine and associated consumables to contractors;
- (d) requirements that the contractor undertakes to—
 - (i) adopt a proactive approach to offering the H1N1 vaccine, with a view to maximising uptake of the vaccine, which includes adopting—
 - (aa) robust call and reminder systems to contact patients in priority groups; and
 - (bb) a programme of opportunistic vaccination of the patients in priority groups;
 - (ii) offer the H1N1 vaccine only to patients in a priority group;
 - (iii) vaccinate patients, in so far as is practicable, in accordance with the following order of priority—
 - (aa) patients in the priority group specified in direction 4(a);
 - (bb) patients in the priority group specified in direction 4(b);
 - (cc) patients in the priority group specified in direction 4(c); and

- (dd) patients in the priority group specified in direction 4(d);
- (e) a requirement that the contractor takes all reasonable steps to ensure that the lifelong medical records held by the contractor are kept up-to-date with regard to the patient's immunisation status, and in particular 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 where a person has consented on a child's behalf, that person's relationship to the child 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 any injection site of each vaccine;
 - (ee) any contraindications to the vaccination; and
 - (ff) any adverse reactions to the vaccination;
- (f) a requirement that the contractor ensures that any health care professional who is involved in administering a vaccine has—
 - (i) the necessary experience, skills and training with regard to the administration of the vaccine; and
 - (ii) training with regard to the recognition and initial treatment of anaphylaxis;
- (g) a requirement that the contractor ensures that—
 - (i) all vaccines are stored in accordance with the manufacturer's instructions; and
 - (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;
- (h) a requirement that the contractor supplies the Regional Board with such information as it may reasonably request for the purposes of monitoring the uptake of the Pandemic Flu Vaccine (H1N1) 2009.

(2) The arrangements that the Regional Board makes as part of its Pandemic Influenza (H1N1) Vaccination Scheme must include arrangements for ensuring that it is notified when patients on any housebound patients lists are vaccinated in order to enable it to make appropriate payments, in accordance with direction 7, to the contractor on whose registered patient list those patients are registered, and those arrangements must include—

- (a) a requirement that where the contractor is vaccinating a patient who is not on a registered patient list held by that contractor, the contractor must ask the patient for the name and address of the general medical services contractor on whose registered list of patients they appear, if any; and
- (b) a requirement that if the patient provides any information requested in accordance with sub-paragraph (a), the contractor must provide the Regional Board with such information which it reasonably requests in support of any claim by the contractor in respect of that patient,

and may include any other provisions the Regional Board considers reasonably necessary in order to enable it to make appropriate payments, in accordance with direction 7, to the contractor on whose registered patient list those patients are registered.

(3) The termination provisions in relation to the contractual arrangements in relation to the Pandemic Influenza (H1N1) Vaccination Scheme must—

- (a) in all cases provide that either party may withdraw from the arrangements entered into as part of the Regional Board Pandemic Influenza (H1N1) Vaccination Scheme by giving 21 days notice in writing, and
- (b) if the contractual arrangements relating to the Regional Board Pandemic Influenza (H1N1) Vaccination Scheme comprise only part of the arrangements that the contractor has made with the Regional Board to provide primary medical services, the provisions

providing for termination of the Pandemic Influenza (H1N1) Vaccination Scheme arrangements by giving 21 days notice must be in addition to any other termination provisions under those other arrangements.

The amount of payments relating to the Pandemic Influenza (H1N1) Vaccination Scheme in the case of contractors with a registered patient list

7.—(1) The arrangements that the Regional Board, as part of its Pandemic Influenza (H1N1) Vaccination Scheme, enters into with contractors must provide for the payments specified in paragraph (2) to be made.

(2) In respect of each completed vaccination for a member of any priority group on the contractor's registered patient list, the amount is £5.25 (where the appropriate dosage is two doses of the H1N1 vaccine, that is £5.25 per vaccination, but £5.25 is payable for the first completed vaccination even if the patient does not receive the second dose).

(3) The amount specified in paragraph (2) is payable to the contractor under the arrangements even if—

- (a) the patient vaccinated is on the housebound patients list prepared pursuant to direction 6(1)(a) and as a consequence the completed vaccination is not administered by the contractor, provided the vaccination is nevertheless administered under arrangements entered into as part of the Regional Boards Pandemic Influenza (H1N1) Vaccination Scheme; or
- (b) the patient vaccinated was vaccinated before the contractual arrangements were entered into, provided—
 - (i) the contractor was responsible for administering the vaccine, and
 - (ii) the patient to whom the vaccine was administered was a patient to whom the contractor would have been obliged to offer the vaccine under the arrangements subsequently entered into, had that vaccine not already been administered.

Part 2

Amendment of the Statement of Financial Entitlements

8. The SFE is amended as follows.

Amendments to Section 4

9. Section 4 (quality and outcome framework: general) is amended as follows—

(1) for paragraph 4.15 (calculation of points in the patient experience domain), substitute the following—

“4.15 This domain, in Section 4 of the QOF, contains three indicators, all of which relate to patient experience: the first is about the length of patient consultations and the second and third indicators are about patient experience of access. The method of calculating the number of points earned under the indicator relating to the length of patient consultations is set out in paragraph 4.16. The method of calculating the number of points earned under the indicators relating to patient experience of access is set out in paragraphs 4.17 to 4.18E. There are specific provisions in paragraph 4.18BA to 4.18BC in relation to the calculation of such points in respect of the financial year 2009/2010 for those contractors who enter into arrangements with the Regional Board to participate in the Regional Boards Pandemic Influenza (H1N1) Vaccination Scheme established in accordance with the Pandemic Influenza (H1N1) Vaccination Directions 2009”;

(2) after paragraph 4.18B, insert the following—

“4.18BA If the contractor has on or before 31st March 2010 entered into arrangements with the Regional Board to participate in the Regional Boards Pandemic Influenza (H1N1) Vaccination Scheme established in accordance with the Pandemic Influenza (H1N1) Vaccination Directions

2009 the Regional Board must, as soon as practicable after 31st March 2010, calculate the percentage of those of the contractor's registered patients who are in the priority group specified in Direction 4(a) of the Pandemic Influenza (H1N1) Vaccination Directions 2009 who have been vaccinated or are deemed to have been vaccinated under those arrangements by the contractor. For these purposes—

- (a) a patient is vaccinated under those arrangements by the contractor if they have received the appropriate dosage as recommended in the Vaccination schedule contained in CMOs letter, HSS (MD) 47/2009, of 15th October 2009, set out at (c) below; and
- (b) a patient is deemed to have been vaccinated under those arrangements by the contractor if—
 - (i) they are on the contractor's housebound patient list (as defined in the Pandemic Influenza (H1N1) Vaccination Directions 2009) and have received the appropriate dosage as set out in the Vaccination schedule contained in CMOs letter, HSS (MD) 47/2009, of 15th October 2009, even if those vaccinations were not administered by the contractor; or
 - (ii) they were vaccinated before the arrangements were entered into, provided the contractor was responsible for administering the vaccine, and the patient to whom the vaccine was administered was a patient to whom the contractor would have been obliged to offer the vaccine under the arrangements subsequently entered into, had that vaccine not already been administered.

(c) Vaccine schedule

Following advice from the Joint Committee on Vaccination and Immunisation (JCVI), the following vaccination schedule is recommended in Northern Ireland:

Pandemrix (manufactured by GSK)

For all children aged from 6 months of age to less than 10 years of age (9 years, 364 days):

Two half doses (0.25ml) of Pandemrix should be given with a minimum of three weeks between doses.

For individuals aged from 10 years to less than 60 years of age (59 years, 364 days):

One dose (0.5ml) of Pandemrix.

For individuals aged 60 years and over

One dose (0.5ml) of Pandemrix. (this advice will be reviewed when more data becomes available)

For immunocompromised individuals aged 10 years and over

Two doses (0.5ml) of Pandemrix should be given with a minimum of three weeks between doses.

Celvapan (manufactured by Baxter)

For children from 6 months of age and adults

Two doses (0.5ml) of Celvapan should be given with a minimum of three weeks between doses.”

4.18BB “GPs will seek to achieve a swine flu vaccination uptake of at least, or better than, that achieved by the practice for seasonal flu on 2008/09, however if the percentage of patients in the At Risk groups registered with the practice calculated in accordance with section 4.18BA is greater than 50.7%,—

the contractor's points in respect of indicators PE7 for the financial year 2009/2010 will be calculated in accordance with the provisions of this Section but as though the minimum percentage threshold set out in Annex D in respect of that indicator was 50% and as though the maximum percentage threshold set out in Annex D in respect of that indicator were 80%; and

the contractor's points in respect of indicators PE8 for the financial year 2009/2010 will be calculated in accordance with the provisions of this Section but as though the minimum percentage threshold set out in Annex D in respect of that indicator was 40% and as though the maximum percentage threshold set out in Annex D in respect of that indicator were 80%.

4.18BC If the percentage so calculated is 50.7% or less, or if the contractor has not on or before 31st March 2010 entered into arrangements with the Regional Board to participate in the Regional

Board Pandemic Influenza (H1N1) Vaccination Scheme established in accordance with the Pandemic Influenza (H1N1) Vaccination Directions 2009, the contractor's points in respect of indicators PE7 and PE8 for the financial year 2009/2010 will be calculated in accordance with the provisions of this Section and on the basis of the financial thresholds set out in Annex D.”; and

(3) for paragraph 4.18C, substitute the following—

“4.18C If a contractor has achieved a percentage result in relation to either indicator that is the minimum set for that indicator or is below that minimum (subject to any adjustment required in respect of the financial year 2009/2010 in accordance with paragraphs 4.18BA and 4.18BB), it achieves no points in relation to that indicator. If a contractor has achieved a percentage result in relation to either indicator that is between the minimum and the maximum set for that indicator (subject to any adjustment required in respect of the financial year 2009/2010 in accordance with paragraphs 4.18BA and 4.18BB), it achieves a proportion of the points available in relation to that indicator. The proportion is calculated as follows.”.

Amendment to section 8

10. Section 8 (Childhood Immunisations Scheme) is amended as follows

(1) in paragraph 8.10, after the words “unless the information the Regional Board needs to calculate the payment is supplied late” and immediately before the table, insert the following—

“Specific provision applies in respect of the calculation of TYOIP in relation to quarter 3 of the financial year 2009/2010 i.e. the quarter commencing on 1st October 2009. If the contractor has before 31st December 2009 entered into arrangements with the Regional Board to participate in the Regional Board Pandemic Influenza (H1N1) Vaccination Scheme established in accordance with the Pandemic Influenza (H1N1) Vaccination Directions 2009, the final date for immunisations which count towards the payment for that quarter will be 10th February 2010 and not 31st December 2009 as would normally be required in accordance with the table below.”; and

(b) after paragraphs 8.20, insert the following—

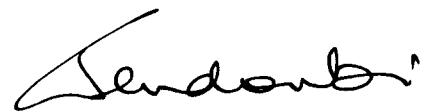
“Specific provision applies in respect of the calculation of FYOIP in relation to quarter 3 of the financial year 2009/2010 i.e. the quarter commencing on 1st October 2009. If the contractor has before 31st December 2010 entered into arrangements with the Regional Board to participate in the Regional Board Pandemic Influenza (H1N1) Vaccination Scheme established in accordance with the Pandemic Influenza (H1N1) Vaccination Directions 2009, the final date for immunisations which count towards the payment for that quarter will be 10th February 2010 and not 31st December 2009 as would normally be required in accordance with the table in paragraph 8.10.”.

Amendment of Annex A

11. In Part 2 of Annex A (Glossary – Definitions), after the definition of “Non-GP provider”, insert the following definition—

““Pandemic Influenza (H1N1) Vaccination Directions 2009” means the Primary Medical Services (Directed Enhanced Services) Pandemic Influenza (H1N1) Vaccination Scheme) and Statement of Financial Entitlements (Amendment) Directions (Northern Ireland) 2009;”.

Signed on behalf of the Department of Health, Social Services and Public Safety on 6th November 2009



Christine Jendoubi

Senior Officer of the Department of Health, Social Services and Public Safety

Clinical risk groups

Clinical risk groups	Examples (decision based on clinical judgement)
<p>Chronic respiratory disease and asthma that requires continuous or repeated use of inhaled or systemic steroids or with previous exacerbations requiring hospital admission</p>	<ul style="list-style-type: none"> • Chronic obstructive pulmonary disease (COPD) including chronic bronchitis and emphysema; bronchiectasis, cystic fibrosis, interstitial lung fibrosis, pneumoconiosis and bronchopulmonary dysplasia (BPD) • Children who have previously been admitted to hospital for lower respiratory tract disease
<p>Chronic heart disease</p>	<ul style="list-style-type: none"> • Congenital heart disease • Hypertension with cardiac complications • Chronic heart failure • Individuals requiring regular medication and/or follow-up for ischaemic heart disease
<p>Chronic renal disease</p>	<ul style="list-style-type: none"> • Chronic renal failure • Nephrotic syndrome • Renal transplantation
<p>Chronic liver disease</p>	<ul style="list-style-type: none"> • Cirrhosis • Biliary artesia • Chronic hepatitis
<p>Chronic neurological disease*</p>	<ul style="list-style-type: none"> • Stroke • Transient ischaemic attack (TIA)
<p>Diabetes</p>	<ul style="list-style-type: none"> • Type 1 diabetes • Type 2 diabetes requiring insulin or oral hypoglycaemic drugs • Diet controlled diabetes

Immunosuppression	<ul style="list-style-type: none">• Immunosuppression due to disease or treatment• Patients undergoing chemotherapy leading to immunosuppression• Asplenia or splenic dysfunction• HIV infection• Individuals treated with or likely to be treated with systemic steroids for more than a month at a dose equivalent to prednisolone at 20mg or more per day (any age) or for children under 20kg a dose of 1mg or more per kg per day.• some immunocompromised patients may have a suboptimal immunological response to the vaccine
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