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STATUTORY INSTRUMENTS

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**2009 No. 2230**

**NATIONAL HEALTH SERVICE, ENGLAND**

**The National Health Service (Prescribing and Charging  
Amendments Relating to Pandemic Influenza) Regulations 2009**

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|-------------------------------|---------|-------------------------|
| <i>Made</i>                   | - - - - | <i>17th August 2009</i> |
| <i>Laid before Parliament</i> |         | <i>20th August 2009</i> |
| <i>Coming into force</i>      | - -     | <i>21st August 2009</i> |

The Secretary of State makes the following Regulations in exercise of the powers conferred by sections 88, 89, 94, 172, 182, 184(1), 272(7) and (8) and 275(1) of the National Health Service Act 2006(1).

**Citation, commencement and application**

1.—(1) These Regulations may be cited as the National Health Service (Prescribing and Charging Amendments Relating to Pandemic Influenza) Regulations 2009 and come into force on 21st August 2009.

(2) These Regulations apply in relation to England.

**Amendment of the National Health Service (Charges for Drugs and Appliances) Regulations 2000**

2. In the National Health Service (Charges for Drugs and Appliances) Regulations 2000(2), after regulation 7B(3), insert the following regulation—

**“Exemption from charges in respect of listed medicines**

7C.—(1) No patient shall be liable to pay a charge under these Regulations in respect of the following medicines—

- (a) oseltamivir (marketed as Tamiflu);
- (b) zanamivir (marketed as Relenza),

in the circumstances set out in paragraph (2).

(2) Those circumstances are that—

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(1) [2006 c.41](#). By virtue of section 271 of the Act, the powers conferred by these sections are exercisable by the Secretary of State only in relation to England. Section 275(1) is cited for the definitions of “prescribed” and “regulations”.

(2) [S.I. 2000/620](#).

(3) Regulation 7B was inserted by [S.I. 2008/571](#).

- (a) the Secretary of State has made arrangements for supplying the medicine to patients free of charge; or
  - (b) the NHS body that is responsible for the arrangements under which the medicine is supplied has made arrangements, with the approval of the Secretary of State, for supplying the medicine to patients free of charge,
- and the patient is supplied with the medicine under those arrangements.”.

### **Amendment of the National Health Service (General Medical Services Contracts) Regulations 2004**

3. In the National Health Service (General Medical Services Contracts) Regulations 2004<sup>(4)</sup>—
- (a) in regulation 2<sup>(5)</sup> (interpretation), in paragraph (1), after the definition of “limited partnership” insert the following definitions—
    - ““listed medicine” means a medicine mentioned in regulation 7C(1) of the National Health Service (Charges for Drugs and Appliances) Regulations 2000;
    - “listed medicines voucher” means a form provided by a Primary Care Trust for use for the purpose of ordering a listed medicine;”;
  - (b) in paragraph 38<sup>(6)</sup> of Schedule 6 (other contractual terms – prescribing)—
    - (i) in sub-paragraph (a), omit “and”,
    - (ii) in sub-paragraph (b), for “professional,” substitute “professional, and”, and
    - (iii) after sub-paragraph (b), insert the following sub-paragraph—
      - “(c) any listed medicines voucher issued by a prescriber or any other person acting under the contract;”;
  - (c) in paragraph 39<sup>(7)</sup> of Schedule 6 (other contractual terms – prescribing)—
    - (i) in sub-paragraph (1), after “sub-paragraph (1A)” insert “and (1B)”, and
    - (ii) after sub-paragraph (1A), insert the following sub-paragraphs—
      - “(1B) During an outbreak of an illness for which a listed medicine may be used for treatment or for prophylaxis, if—
        - (a) the Secretary of State or the Primary Care Trust has made arrangements for the distribution of a listed medicine in the area of the Primary Care Trust free of charge; and
        - (b) that listed medicine is needed for treatment or prophylaxis of any patient who is receiving treatment under the contract,a prescriber may, or if the patient has not attained the age of 13 years must, order that listed medicine by using a listed medicines voucher, which the prescriber must sign.
      - (1C) During an outbreak of an illness for which a listed medicine may be used for treatment or for prophylaxis, if—
        - (a) the Secretary of State or the Primary Care Trust has made arrangements for the distribution of a listed medicine in the area of the Primary Care Trust free of charge;

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(4) S.I. 2004/291.

(5) Amended by S.I. 2004/2694, 2005/893, 3315 and 3491, 2006/1501, 2007/289 and 3491, and 2008/528 and 1700.

(6) Substituted by S.I. 2007/3491.

(7) Amended by S.I. 2005/893 and 2007/3491.

- (b) those arrangements contain criteria set out in a protocol which enable persons who are not prescribers to identify the symptoms of, and whether there is a need for treatment or prophylaxis of, that disease;
  - (c) a person acting on behalf of the contractor, who is not a prescriber but who is authorised to order listed medicines by the Primary Care Trust, has applied the criteria referred to in paragraph (b) to any patient who is receiving treatment under the contract; and
  - (d) having applied the criteria, the person acting on behalf of the contractor has concluded that the listed medicine is needed for treatment or prophylaxis of that patient,
- the person acting on behalf of the contractor must order that listed medicine by using a listed medicines voucher, which the person ordering the listed medicine must sign.”;
- (d) in paragraph 42(8) of Schedule 6 (other contractual terms – restrictions on prescribing by medical practitioners)—
    - (i) in sub-paragraph (1), after “shall not order on” insert “a listed medicines voucher,”, and
    - (ii) in sub-paragraph (2)—
      - (aa) after “shall not order on” insert “a listed medicines voucher,”,
      - (bb) for paragraph (c) substitute the following paragraph—
        - “(c) if the order is on a prescription form, the practitioner includes—
          - (i) the reference “SLS”, or
          - (ii) if the order is under arrangements made by the Secretary of State or the Primary Care Trust for the distribution of a listed medicine free of charge, the reference “ACP”,”; and
  - (e) in paragraph 43(9) of Schedule 6 (other contractual terms – restrictions on prescribing by supplementary prescribers), in sub-paragraph (2)(d)(iii), for “prescription, he includes on the prescription form the reference “SLS”” substitute “prescription on a prescription form, the prescriber includes on the form the reference “SLS” or, in the case of a listed medicine ordered under arrangements made by the Secretary of State or the Primary Care Trust for the medicine’s distribution free of charge, the reference “ACP””.

#### **Amendment of the National Health Service (Personal Medical Services Agreements) Regulations 2004**

**4.** In the National Health Service (Personal Medical Services Agreements) Regulations 2004(10)—

- (a) in regulation 2(11) (interpretation), in paragraph (1), after the definition of “licensing body” insert the following definitions—
  - ““listed medicine” means a medicine mentioned in regulation 7C(1) of the National Health Service (Charges for Drugs and Appliances) Regulations 2000;
  - “listed medicines voucher” means a form provided by a Primary Care Trust for use for the purpose of ordering a listed medicine;”;

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(8) Amended by S.I. 2005/893.

(9) Amended by S.I. 2005/893.

(10) S.I. 2004/627.

(11) Amended by S.I. 2004/2694, 2005/893, 3315 and 3491, 2006/1501, 2007/289 and 3491, and 2008/528 and 1700.

- (b) in paragraph 37(12) of Schedule 5 (other contractual terms – prescribing), in sub-paragraph (1)—
  - (i) at the end of paragraph (a), omit “and”,
  - (ii) in paragraph (b), for “professional,” substitute “professional; and”, and
  - (iii) after paragraph (b), insert the following paragraph—
    - “(c) any listed medicines voucher issued by a prescriber or any other person acting under the contract,”;
- (c) in paragraph 38(13) of Schedule 5 (other contractual terms – prescribing)—
  - (i) in sub-paragraph (1), after “sub-paragraph (1A)” insert “and (1B)”, and
  - (ii) after sub-paragraph (1A), insert the following sub-paragraphs—
    - “(1B) During an outbreak of an illness for which a listed medicine may be used for treatment or for prophylaxis, if—
      - (a) the Secretary of State or the Primary Care Trust has made arrangements for the distribution of a listed medicine in the area of the Primary Care Trust free of charge; and
      - (b) that listed medicine is needed for treatment or prophylaxis of any patient who is receiving treatment under the contract,a prescriber may, or if the patient has not attained the age of 13 years must, order that listed medicine by using a listed medicines voucher, which the prescriber must sign.
    - (1C) During an outbreak of an illness for which a listed medicine may be used for treatment or for prophylaxis, if—
      - (a) the Secretary of State or the Primary Care Trust has made arrangements for the distribution of a listed medicine in the area of the Primary Care Trust free of charge;
      - (b) those arrangements contain criteria set out in a protocol which enable persons who are not prescribers to identify the symptoms of, and whether there is a need for treatment or prophylaxis of, that disease;
      - (c) a person acting on behalf of the contractor, who is not a prescriber but who is authorised to order listed medicines by the Primary Care Trust, has applied the criteria referred to in paragraph (b) to any patient who is receiving treatment under the contract; and
      - (d) having applied the criteria, the person acting on behalf of the contractor has concluded that the listed medicine is needed for treatment or prophylaxis of that patient,the person acting on behalf of the contractor must order that listed medicine by using a listed medicines voucher, which the person ordering the listed medicine must sign.”;
- (d) in paragraph 41(14) of Schedule 5 (other contractual terms – restrictions on prescribing by medical practitioners)—
  - (i) in sub-paragraph (1), after “shall not order on” insert “a listed medicines voucher,”, and
  - (ii) in sub-paragraph (2)—

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(12) Substituted by S.I. 2007/3491.

(13) Amended by S.I. 2004/2694, 2005/893 and 2007/3491.

(14) Amended by S.I. 2005/893.

- (aa) after “shall not order on” insert “a listed medicines voucher,” and
- (bb) for paragraph (c) substitute the following paragraph—
  - “(c) if the order is on a prescription form, the practitioner includes—
    - (i) the reference “SLS”, or
    - (ii) if the order is under arrangements made by the Secretary of State or the Primary Care Trust for the distribution of a listed medicine free of charge, the reference “ACP”,”; and
- (e) in paragraph 42(15) of Schedule 5 (other contractual terms – restrictions on prescribing by supplementary prescribers), in sub-paragraph (2)(d)(iii), for “prescription, he includes on the prescription form the reference “SLS”” substitute “prescription on a prescription form, the prescriber includes on the form the reference “SLS” or, in the case of a listed medicine ordered under arrangements made by the Secretary of State or the Primary Care Trust for the medicine’s distribution free of charge, the reference “ACP””.

#### **Amendment of the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004**

5. In Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004(16) (drugs, medicines and other substances that may only be ordered in certain circumstances)—

- (a) in the entry for “Oseltamivir (Tamiflu)”—
  - (i) in the part which relates to “treatment of influenza” (as mentioned in column 3), in column 2, after paragraph (1) insert—

“(1A) Any patient suffering from influenza during an outbreak of pandemic influenza (influenza caused by a new virus subtype that has an increased and sustained transmission during a global outbreak of influenza), where the drug is ordered under arrangements for the distribution of the drug free of charge which are approved by the Secretary of State or are part of a Primary Care Trust’s antivirals distribution service(17).”;
  - (ii) in the part which relates to “prophylaxis of influenza” (as mentioned in column 3), in column 2, after paragraph (2) insert—

“(2A) Any patient at risk from influenza during an outbreak of pandemic influenza (influenza caused by a new virus subtype that has an increased and sustained transmission during a global outbreak of influenza), where the drug is ordered under arrangements for the distribution of the drug free of charge which are approved by the Secretary of State or are part of a Primary Care Trust’s antivirals distribution service.”;
- (b) in the entry for “Zanamivir (Relenza)”—
  - (i) number the current paragraph for the entry in column 2 as “(1)”, and then after that paragraph add the following paragraph—

“(2) Any patient at risk of or suffering from influenza during an outbreak of pandemic influenza (influenza caused by a new virus subtype that has an increased and sustained transmission during a global outbreak of influenza), where the drug is

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(15) Amended by S.I. 2005/893.

(16) S.I. 2004/629; Schedule 2 has been amended by S.I. 2004/3215.

(17) The directions to Primary Care Trusts in England requiring them to establish such services, the Functions of Primary Care Trusts (Antiviral Distribution for Pandemic Influenza) (No. 2) Directions 2009, signed on 1st July 2009, have been published on the Department of Health’s website, [www.dh.gov.uk](http://www.dh.gov.uk).

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ordered under arrangements for the distribution of the drug free of charge which are approved by the Secretary of State or are part of a Primary Care Trust's antivirals distribution service.", and

- (ii) in column 3, opposite paragraph (2) in column 2, insert—  
“Prophylaxis or treatment of influenza.”.

Signed by authority of the Secretary of State for Health.

17th August 2009

*Gillian Merron*  
Minister of State,  
Department of Health

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## EXPLANATORY NOTE

*(This note is not part of the Regulations)*

These Regulations further amend the National Health Service (Charges for Drugs and Appliances) Regulations 2000 (“the Charges Regulations”), the National Health Service (General Medical Services Contracts) Regulations 2004 (“the GMS Regulations”), the National Health Service (Personal Medical Services Agreements) Regulations 2004 (“the PMS Regulations”) and the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc.) Regulations 2004 (“the Drugs Regulations”).

Regulation 2 inserts a new exemption into the Charges Regulations, the new regulation 7C, the effect of which is that two named antiviral medicines will be exempt from the charging arrangements in the Charges Regulations, if distributed under arrangements for their free supply made by the Secretary of State or a relevant National Health Service body (with the approval of the Secretary of State).

Regulations 3 and 4 amend the GMS Regulations and the PMS Regulations so that during outbreaks of pandemic influenza, orders for the same two antiviral medicines for patients aged 13 and over can be written either on a new voucher or on the standard prescription form (in the latter case, with the endorsement “ACP”), where these medicines are being ordered by qualified prescribers under arrangements made by the Secretary of State or a Primary Care Trust for the distribution of these medicines free of charge. However, a qualified prescriber must use the new voucher for an order under those arrangements, if the order is for a patient aged 12 or under.

Amendments are also made to provide for the ordering of these medicines by authorised people who are not qualified prescribers, if they are following criteria which enable them to do so and which are set under the arrangements for free distribution. However, any people ordering these medicines who are not qualified prescribers must use the new voucher rather than the standard prescription form.

Regulation 5 amends the entries for the same two antiviral medicines in Schedule 2 to the Drugs Regulations, with the effect of widening the circumstances under which they may be ordered for patients under general medical services contracts and personal medical services agreements. Essentially, they may be ordered during outbreaks of pandemic influenza for treatment or prophylaxis of influenza, where this is under arrangements for the distribution of the medicines free of charge which are approved by the Secretary of State or are part of a Primary Care Trust’s antivirals distribution service.