SCOTTISH STATUTORY INSTRUMENTS

2009 No. 177

NATIONAL HEALTH SERVICE

The National Health Service (Pharmaceutical Services, Charges for Drugs and Appliances and Charges to Overseas Visitors) (Scotland) Amendment Regulations 2009

Made Laid before the Scottish	7th May 2009
Parliament	8th May 2009
Coming into force	8th May 2009

The Scottish Ministers make the following Regulations in exercise of the powers conferred by sections 27(1), (2), (3) and (4), 69(1), 75A, 98, 105(7) and 108(1) of the National Health Service (Scotland) Act 1978(1) and all other powers enabling them to do so.

Citation and commencement

1. These Regulations may be cited as the National Health Service (Pharmaceutical Services, Charges for Drugs and Appliances and Charges to Overseas Visitors) (Scotland) Amendment Regulations 2009 and come into force on 8th May 2009.

¹⁹⁷⁸ c. 29; section 27(1) was amended by the Health Services Act 1980 (c. 53) ("the 1980 Act"), section 20(2), the National (1)Health Service and Community Care Act 1990 (c. 19) ("the 1990 Act"), Schedule 9, paragraph 19(7)(a), the Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), section 3, the National Health Services (Primary Care) Act 1997 (c. 46) ("the 1997 Act"), Schedule 2, Part 1, paragraph 44 and the Health and Social Care Act 2001 (c. 15) ("the 2001 Act"), section 44(2); section 27(2) was substituted by the National Health Service (Amendment) Act 1986 (c. 66) ("the 1986 Act"), section 3(3) and amended by the 1990 Act, Schedule 9, paragraph 19(7)(b); section 27(3) was amended by the 1990 Act, Schedule 9, paragraph 19(7)(c); section 27(4) was amended by the 1990 Act, Schedule 9, paragraph 19(7)(c) and (d) and S.I.2007/289; section 75A was inserted by the Social Security Act 1988 (c. 7), section 14(2), and amended by the Health and Medicines Act 1988 (c. 49) ("the 1988 Act"), Schedule 2, paragraph 13, the 1997 Act, Schedule 2, Part I, paragraphs 32 and 50, and the 1990 Act, Schedule 9, paragraph 19(13), and by S.I. 1998/2358; section 98 was amended by the 1988 Act, section 7(13) and (14), section 105(7) was amended by the 1980 Act, Schedule 6, paragraph 5(1) and Schedule 7, the Health and Social Services and Social Security Adjudications Act 1983 (c. 41), Schedule 9, Part I, paragraph 24 and the 1999 Act, Schedule 4, paragraph 60; section 108(1) contains definitions of "prescribed" and "regulations" relevant to the exercise of the statutory powers under which these Regulations are made. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c. 46)

Amendment of the National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995

2.—(1) The National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995(2) are amended as follows.

(2) In regulation 2(1) (interpretation and application), insert at the appropriate place-

""emergency requiring the flexible provision of pharmaceutical services" means an emergency declared by means of a direction to Boards under section 2(5) of the Act to the effect that, as a result of the threatened damage to human welfare caused or which may be caused by the illness designated in the direction, Boards must for a specified period exercise one or more of their functions under regulation 5ZA or regulation 8(7), subject to any conditions or limitations set out in the direction;".

(3) After regulation 5 (pharmaceutical list), insert-

"Temporary relocations and additional premises

5ZA.—(1) Regulation 5(2)(b), (4), (6), (7), (8), (10), (11) and (14) shall not apply to an application for a temporary amendment to the pharmaceutical list which the Board is satisfied is necessary or desirable because of an emergency requiring the flexible provision of pharmaceutical services.

(2) In the circumstances described in paragraph (1), the Board may make a temporary amendment to an entry in the pharmaceutical list, but–

- (a) only for a specified period (which shall not be for longer than the specified period for the duration of the emergency given by the Scottish Ministers) which the Board may extend or curtail in appropriate circumstances; and
- (b) the applicant may revert to the applicant's original entry in the pharmaceutical list before the end of the specified period, on giving the Board at least 24 hours notice.
- (3) Where-
 - (a) a direction is given under section 2(5) of the Act which contains a declaration of an emergency requiring the flexible provision of pharmaceutical services; and
 - (b) the Scottish Ministers issue a further direction under that section changing the specified period of the duration of the emergency,

for the purposes of these Regulations, the duration of the emergency is to be construed in accordance with the specified period as revised by the Scottish Ministers.".

(4) After regulation 8(6) (schemes for securing proper pharmaceutical service) insert-

"(7) During an emergency requiring the flexible provision of pharmaceutical services, a Board may agree with any person whose name is included in a pharmaceutical list that the provisions of a scheme prepared under paragraph (3) shall not apply to that person for the duration of the emergency."

(5) After regulation 11(5) (publication of particulars) insert-

"(6) Paragraph (5) shall not apply to alterations in a pharmaceutical list made by a Board in terms of regulation 5ZA(2)."

- (6) In Schedule 1 (terms of service for pharmacists)-
 - (a) in paragraph 3 (provision of pharmaceutical services)-

⁽²⁾ S.I. 1995/414, as amended by S.I. 1996/840 and 1504, 1997/696, 1998/2224 and 3031, S.S.I. 1999/57, 2001/70, 2002/111, 2003/296, 2004/39 and 212, S.I. 2004/1771, S.S.I. 2005/327 and 618, 2006/143, 245 and 320, S.I. 2007/289 and S.S.I. 2007/208, 390 and 500 and 2008/27.

(i) in sub-paragraph (2) after "shall not" insert-

", except for the duration of an emergency requiring the flexible provision of pharmaceutical services,";

(ii) in sub-paragraph (3) after "shall not" insert-

", except for the duration of an emergency requiring the flexible provision of pharmaceutical services,";

- (iii) in sub-paragraph (11), for "and (6)" substitute ", (6) and (17)"; and
- (iv) after sub-paragraph (16) insert-

"(17) A pharmacist may dispense a drug where the conditions for urgent supply specified in paragraph (4) of article 8 of the Prescription Only Medicines (Human Use) Order 1997(**3**) are satisfied, before receiving a prescription form, if the pharmacist is satisfied that it is appropriate to do so."; and

(b) in paragraph 4 (premises and hours of business)-

(i) in sub-paragraph (1) insert at the beginning "Subject to regulation 8(7)"; and

(ii) in sub-paragraph (4) insert at the beginning "Subject to regulation 5ZA".

Amendment of the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2008

3.—(1) The National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2008(**4**) are amended as follows.

- (2) In regulation 7(2) (exemptions)-
 - (a) delete "or" at the end of sub-paragraph (b);
 - (b) in sub-paragraph (c) for "by" substitute "to"; and
 - (c) after sub-paragraph (c) insert-

"; or

- (d) the supply is of drugs or preparations for the treatment of Pandemic Influenza (defined as "phase 6" in the World Health Organisation's ("WHO") influenza pandemic phases), or Influenza that might become pandemic (defined as "phase 4" or "phase 5" by WHO) specified in Part 2 of Schedule 2.".
- (3) In Schedule 2-
 - (a) after "SCHEDULE 2", insert-"PART 1"
 - (b) after "Pyridoxine", insert-

"PART 2

SCHEDULE OF DRUGS TO TREAT INFLUENZA

4. The following drugs to treat Pandemic Influenza, or Influenza that might become pandemic:

Oseltamivir

Zanamivir"

⁽³⁾ S.I. 1997/1830. Article 8 was amended by S.I. 1998/2081, 2002/549, 2003/696, 2006/915 and 2008/1161.

⁽⁴⁾ S.S.I. 2008/27, as amended by S.S.I. 2008/105 and 2009/37.

Amendment of the National Health Service (Charges to Overseas Visitors) (Scotland) Regulations 1989

4.—(1) The National Health Service (Charges to Overseas Visitors) (Scotland) Regulations 1989(**5**) are amended as follows.

(2) In Schedule 1 (diseases for the treatment of which no charge is to be made), after "Mumps" insert-

"Pandemic Influenza (defined as "phase 6" in the World Health Organisation's ("WHO") influenza pandemic phases), or Influenza that might become pandemic (defined as "phase 4" or "phase 5" by WHO).".

St Andrew's House, Edinburgh 7th May 2009

NICOLA STURGEON A member of the Scottish Executive

(5) S.I. 1989/364; amended by S.I. 1992/411, 1994/1770, 1998/251 and S.S.I. 2004/369, 2006/141 and 2008/290.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995 to provide that in the case of an emergency requiring the flexible provision of pharmaceutical services, (for example, pandemic influenza), arrangements are put in place to enable pharmacists to relocate temporarily, or take on additional premises, without needing to go through the normal applications process, where it is reasonable to do so, without breaching their arrangements with the Health Boards.

These Regulations also amend the National Health Service (Charges for Drugs and Appliances) (Scotland) Regulations 2008 to provide that no charge will be payable under those regulations for the supply of oseltamivir or zanamivir to treat pandemic influenza or influenza that might become pandemic.

They also amend the National Health Service (Charges to Overseas Visitors) (Scotland) Regulations 1989 to provide that no charge will be payable under those regulations for treatment of pandemic influenza or influenza that might become pandemic.