SCOTTISH STATUTORY INSTRUMENTS

2009 No. 183

The National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009

Citation and commencement

1. These Regulations may be cited as the National Health Service (Pharmaceutical Services) (Scotland) Regulations 2009 and come into force on 1st July 2009.

Interpretation and application

2.—(1) In these Regulations unless the context otherwise requires–

"the Act" means the National Health Service (Scotland) Act 1978;

"the 1968 Act" means the Medicines Act 1968(**1**);

"additional professional services" has the meaning assigned to it in regulation 4;

"advanced electronic signature" means an electronic signature, within the meaning of section 7(2) of the Electronic Communications Act 2000(**2**), which is–

(a) uniquely linked to the signatory;

(b) capable of identifying the signatory;

(c) created using means that the signatory can maintain under his or her sole control; and

(d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable;

"the Agency" means the Common Services Agency for the Scottish Health Service constituted under section 10 of the Act(**3**);

"appliance" means an appliance which is a listed appliance within the meaning of section 27(1) of the Act;

"appropriate non-proprietary name" means a non-proprietary name which is not mentioned in any directions given by the Scottish Ministers under section 17N(6) of the Act (other mandatory contract terms)(**4**) as to the drugs or other substances–

(a) which may not be ordered for patients in the provision of primary medical services under a general medical services contract;

(**1**) 1968 c. 67.
(**2**) 2000 c. 7.
(**3**) Section 10 was amended by the 1980 Act, Schedule 6, paragraph 2, the 1990 Act, Schedule 10, paragraph 1, the Health Act 1999 (c. 8) ("the 1999 Act"), Schedule 4, paragraph 44 and the Health and Social Care (Scotland) Act 2005 (asp 13) ("the 2005 Act"), Schedule 2, paragraph 2.
(**4**) Section 17N was inserted by the Primary Medical Services (Scotland) Act 2004 (asp 1) ("the 2004 Act"), section 4. The current directions are the "Directions as to the drugs, medicines or other substances which may, or may not, be ordered for patients in the provision of primary medical services under a general medical services contract" given on 18th March 2004, and published on Scottish Health on the Web (SHOW) at http://www.show.scot.nhs.uk/sehd/pca/PCA2004(M)11.pdf.

(b) except where the conditions in paragraph 40(2) of Schedule 5 to the GMS Contracts Regulations(**5**) are satisfied, which can only be ordered for specified patients and specified purposes;

"Area Medical Committee" means the committee of that name for the area of a Board recognised under section 9 of the Act(**6**);

"Area Pharmaceutical Committee" means the committee of that name for the area of a Board recognised under section 9 of the Act;

"Board" means a Health Board within the meaning of section 2(1)(a) of the Act(**7**);

"chemical reagent" means a chemical reagent included in a list for the time being approved by the Scottish Ministers for the purposes of section 27 of the Act;

"clinical management plan" has the meaning ascribed in article 1(2) of the Prescription Only Medicines (Human Use) Order 1997(**8**);

"corresponding decision" has the same meaning as in section 32D of the Act(**9**);

"dentist" means a dental practitioner;

"directed services" means additional pharmaceutical services within the meaning of section 27A of the Act;

"doctor" means a fully registered medical practitioner within the meaning of Schedule 1 to the Interpretation Act 1978(**10**);

"drugs" includes medicines and chemical reagents;

"Drug Tariff" has the meaning assigned to it in regulation 12;

"electronic communication" has the same meaning as in section 15 of the Electronic Communications Act 2000(**11**);

"electronic prescription form" means a prescription form as defined in paragraph (b) of the definition of "prescription form";

"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 6 or regulation 11(5), subject to any conditions or limitations set out in the direction;

"ePharmacy service" means the electronic system provided by the Agency by which electronic messages are transmitted between pharmacy contractors, doctors and the Agency;

"equivalent body" means–

(a) in England, a Primary Care Trust, or in relation to any time prior to 1st October 2002 a Health Authority;

(b) in Wales, a Local Health Board or in relation to any time prior to 1st April 2003 a Health Authority;

(**5**) Paragraph 40(2) was amended by S.I.2007/206.
(**6**) Section 9 was amended by the 1990 Act, section 29(4) and (5) and the 1999 Act, Schedule 4, paragraph 43(a) and (b).
(**7**) Section 2(1)(a) was amended by the 1983 Act, Schedule 7, paragraph 1, the 1990 Act, section 28(a), the National Health Service Reform (Scotland) Act 2004 (asp 7), schedule 1, paragraph 1(2) and the 2005 Act, schedule 2, paragraph 2(2).
(**8**) S.I. 1997/1830. The definition of "clinical management plan" was inserted by S.I. 2000/1917.
(**9**) Section 32D was inserted by the 2005 Act, section 27.
(**10**) 1978 c. 30, the definition of "registered medical practitioner" was amended by the Medical Act 1983 (c. 54), Schedule 5, paragraph 18.
(**11**) The definition of "electronic communication" was amended by the Communications Act 2003 (c. 21) Schedule 17, paragraph 158.

(c) in Northern Ireland, a Health and Social Services Board;

or any successor body;

"equivalent list" means a list kept by an equivalent body;

"GMS Contracts Regulations" means the National Health Service (General Medical Services Contracts) (Scotland) Regulations 2004(**12**);

"health centre" means premises provided by the Scottish Ministers in accordance with the provisions of section 36(1)(b) of the Act;

"hypodermic needle exchange services" has the meaning assigned to it in regulation 3(3);

"joint discipline committee" has the same meaning as in the National Health Service (Discipline Committees) (Scotland) Regulations 2006(**13**);

"listed drugs" means such drugs and medicines as are included in a list for the time being approved by the Scottish Ministers for the purposes of section 27(1) of the Act;

"medicinal product" means–

(a) a medicinal product within the meaning given by Article 1 of Directive 2001/83/EC(**14**); or

(b) any product which is not a medicinal product within the meaning given by Article 1 of Directive 2001/83/EC, but which is a medicinal product within the meaning ascribed to it in section 130 of the 1968 Act(**15**);

"minor relocation" has the meaning assigned to it in regulation 5;

"National Appeal Panel" means the panel constituted under Part II of Schedule 4;

"non-electronic prescription form" means a prescription form as defined in paragraph (a) of the definition of "prescription form";

"non-proprietary name" in relation to a drug means–

(a) where the drug is described in a monograph in the current edition in force at the time of the supply of the drug, (as defined in section 103(5) of the 1968 Act)(**16**), of the European Pharmacopoeia, the British Pharmacopoeia, the British Pharmaceutical Codex, the British National Formulary, the International Pharmacopoeia, the Cumulative List of Recommended International Non-proprietary Names or the Dental Practitioners' Formulary, any name, or abbreviation of the name, at the head of that monograph or, where the name consists of two or more words, any name derived from a suitable inversion of such words which is permitted by that publication; or

(b) where the drug is not so described but has an approved name, being the name which appears in the current edition in force at the time of the supply of the drug, (as defined in the said section 103(5) of the 1968 Act) of the list of names prepared and published under section 100 of that Act, its approved name;

"nurse independent prescriber" means a person–

(a) who is registered in the Nursing and Midwifery Register; and

(b) against whose name is recorded in that register an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a community practitioner

(**12**) S.S.I. 2004/115, amended by the Charities and Trustee Investment (Scotland) Act 2005 (asp 10), schedule 4, Part 2, paragraph 18(a), S.S.I. 2004/162 and 215, 2005/337, 2006/247, 2007/206 and 501, 2008/27 and S.I. 2007/289.
(**13**) S.S.I. 2006/330.
(**14**) O.J. No. L 311, 28.11.2001, p.67.
(**15**) Section 130 was amended by the Animal Health and Welfare Act 1984 (c. 40), Schedule 1, paragraph 3 and S.I. 1994/3119, 2005/50 and 2006/2407.
(**16**) Section 103(5) was amended by the 1988 Act, section 22(6).

nurse prescriber, a nurse independent prescriber or a nurse independent/supplementary prescriber;

"Nursing and Midwifery Register" means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(**17**);

"optometrist independent prescriber" means a person–

(a) who is a registered in the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989(**18**), or in the register of visiting optometrists from relevant European States maintained under section 8B(1)(a) of that Act(**19**); and

(b) against whose name is recorded in the relevant register an annotation signifying that he or she is qualified to order drugs, medicines and appliances as an optometrist independent prescriber;

"Patient Group Direction" has the meaning ascribed in Article 1(2) of the Prescription Only Medicines (Human Use) Order 1997(**20**);

"pharmaceutical discipline committee" has the same meaning as in the National Health Service (Discipline Committees) (Scotland) Regulations 2006;

"pharmaceutical list" has the meaning assigned to it in regulation 5;

"pharmaceutical services" means those services as defined by section 27 of the Act and includes the provision to persons who are in a Board's area of listed drugs and medicines which are ordered for those persons by a dental practitioner in pursuance by such dental practitioner of the performance of personal dental services within the meaning of section 1(8) of the National Health Service (Primary Care) Act 1997(**21**) but not including directed services;

"pharmacist" means a person who is registered in Part 1 or 3 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007(**22**) or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976 (**23**);

"pharmacy contractor" means a contractor who provides pharmaceutical services, or a person lawfully conducting a retail pharmacy business in accordance with section 69 of the 1968 Act(**24**), who provides pharmaceutical services in terms of arrangements made by a Board under section 27 of the Act;

"pharmacist independent prescriber" means a pharmacist against whose name in the relevant register is recorded an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"prescriber" means a doctor, a pharmacist independent prescriber, a nurse independent prescriber, an optometrist independent prescriber or a supplementary prescriber under an agreed clinical management plan;

"prescription form" means–

(a) a form provided by the Board or the Agency–

(i) on which the provision of pharmaceutical services may be ordered by–

(**17**) S.I. 2002/253 to which there are no relevant amending instruments.
(**18**) 1989 c. 44; section 7 was amended by S.I. 2005/848.
(**19**) Section 8B was inserted by S.I. 2005/848.
(**20**) The definition of Patient Group Direction was inserted by S.I. 2000/1917.
(**21**) 1997 c. 46.
(**22**) S.I. 2007/289. Article 10(1) was amended by S.I. 2007/3101.
(**23**) S.I. 1976/1213 (N.I. 22).
(**24**) Section 69 was amended by the Statute Law (Repeals) Act 1993 (c. 50), Schedule 1, Part XII, and S.I. 1976/1213 (N.I. 22), 2007/289 and 3101.

(aa) a Board;

(bb) a dentist pursuant to the provisions of his or her terms of service;

(cc) a dentist performing personal dental services in accordance with a pilot under Part I of the National Health Service (Primary Care) Act 1997; or

(dd) a prescriber; and

(ii) which contains on its reverse side a form of declaration of entitlement to exemption or a statement that a charge has been paid to be completed and signed by the patient named on the form or by a person acting on that patient's behalf,

and includes a prescription form provided and issued under equivalent arrangements having effect in England, Wales or Northern Ireland; or

(b) data that are created in an electronic form for the provision of pharmaceutical services ordered by–

(i) a dentist pursuant to the provisions of his or her terms of service;

(ii) a dentist performing personal dental services in accordance with a pilot under Part I of the National Health Service (Primary Care) Act 1997; or

(iii) a prescriber,

and signed with such a person's advanced electronic signature and transmitted as an electronic communication through the ePharmacy service; or

(c) a form on which domiciliary oxygen has been ordered–

(i) by a prescriber in England or Wales for a patient normally resident in England or Wales; and

(ii) in relation to which the patient named on the form (or a person on the patient's behalf) completes and signs a declaration of entitlement to exemption or a statement that a charge has been paid;

"provisional pharmaceutical list" has the meaning assigned to it in regulation 8;

"registered pharmacy" means a registered pharmacy within the meaning of section 74 of the 1968 Act(**25**);

"relevant service" means whole-time service in the armed forces of the Crown in a national emergency or otherwise, or compulsory whole-time service in those forces, including service resulting from any reserve liability, or any equivalent service by a person liable for compulsory whole-time service in those forces;

"restricted availability appliance" means an appliance which is approved for particular categories of persons or for particular purposes only;

"scheduled drug" means–

(a) a drug, medicine or other substance specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug or other substance which may not be ordered in the provision of primary medical services under a general medical services contract; or

(b) except where the conditions in paragraph 40(2) of Schedule 5 to the GMS Contracts Regulations(**26**) are satisfied, a drug, medicine or other substance which is specified in any directions given by the Scottish Ministers under section 17N(6) of the Act as being a drug or other substance which can only be ordered for specified patients and specified

(**25**) Section 74 was amended by the Statute Law (Repeals) Act 1993, Schedule 1, Part XII.
(**26**) Paragraph 40(2) was amended by S.S.I. 2007/206.

purposes in the provision of primary medical services under a general medical services contract;

"supplementary prescriber" means a person whose name is registered in–

(a) the Nursing and Midwifery Register;

(b) Part 1 or 3 of the Register of Pharmacists maintained under article 10(1) of the Pharmacists and Pharmacy Technicians Order 2007,

(c) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976;

(d) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(**27**) relating to–

(i) chiropodists and podiatrists;

(ii) physiotherapists; or

(iii) diagnostic or therapeutic radiographers; or

(e) the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989,

and against whose name is recorded in the relevant register an annotation signifying that he or she is qualified to order drugs, medicines and appliances as a supplementary prescriber or, in the case of the Nursing and Midwifery Register, a nurse independent/supplementary prescriber;

"supply form" means a form issued by a Board to record a supply of pharmaceutical services under the terms of a Patient Group Direction issued by a Health Board in accordance with Article 12C of the Prescription Only Medicines (Human Use) Order 1997(**28**) (exemption for persons conducting a retail pharmacy business who supply or administer prescription only medicines under a Patient Group Direction);

"suspended by direction of the Tribunal" means suspended as respects the provision of pharmaceutical services by a direction of the Tribunal made pursuant to section 32A(2) or section 32B(1) of the Act(**29**) or to any provisions in force in England and Wales or Northern Ireland corresponding to those provisions;

"terms of service" means the terms of service for pharmacists and pharmacy contractors contained or referred to in Schedule 1;

"the Tribunal" means the Tribunal constituted under section 29 of the Act(**30**).

(2) These Regulations shall apply to a person, firm or body corporate (other than a dental practitioner) providing pharmaceutical services (which includes the supply of appliances by appliance suppliers) as they apply to a pharmacist.

(3) Unless the context otherwise requires–

(a) any reference in these Regulations–

(i) to a numbered regulation is a reference to the regulation bearing that number in these Regulations,

(ii) to a numbered Part or Schedule is a reference to the Part of, or Schedule to, these Regulations bearing that number,

(iii) to a form thereby prescribed includes a form substantially the same; and

(**27**) S.I. 2002/254.
(**28**) Article 12C was inserted by S.I. 2000/1917, and amended by S.I. 2000/2899, 2003/696 and 2007/2178.
(**29**) Sections 32A and 32B were inserted by section 8 of the National Health Service (Amendment) Act 1995 (c. 31).
(**30**) Section 29 was amended by the Health and Social Security Act 1984, Schedule 8, Part I and by the National Health Service (Amendment) Act 1995, sections 7 and 9 and the Schedule.

(b) any reference in a regulation or in a Schedule to these Regulations to a numbered paragraph is a reference to the paragraph bearing that number in that regulation or Schedule.

Pharmaceutical services

3.—(1) The arrangements for the provision of pharmaceutical services shall include arrangements for–

(a) the supply of contraceptive substances and appliances;

(b) subject to paragraph (6) the provision of hypodermic needle exchange services.

(2) The arrangements referred to in paragraph (1) shall incorporate the terms of service for pharmacists and pharmacy contractors set out in Schedule 1 to these Regulations.

(3) In these Regulations "hypodermic needle exchange services" means–

(a) the supply, free of charge, by a pharmacy contractor to a person reasonably believed by that pharmacy contractor (if a pharmacist), or a pharmacist employed by that pharmacy contractor, to be a drug misuser, of–

(i) hypodermic needles and syringes;

(ii) equipment for the safe disposal of such needles and syringes; and

(iii) other equipment associated with self-injection.

(b) the receipt by a pharmacy contractor from such a person and the subsequent safe disposal, both free of charge, of any used hypodermic needle or syringe;

(c) the provision of counselling to such a person by a pharmacist.

(4) In paragraph (3) "drug misuser" means a person who is misusing drugs by self-injection.

(5) A pharmacy contractor may at any time give notice in writing to the Board that such pharmacy contractor wishes to be–

(a) included in or excluded from any arrangements for the supply of contraceptive services and appliances; or

(b) included in any arrangements for the provision of hypodermic needle exchange services.

(6) A Board shall agree to a pharmacy contractor providing hypodermic needle exchange services only–

(a) after consulting its most senior pharmaceutical and medical advisers and the Director of Public Health; and

(b) if it is satisfied that such services are necessary or desirable in the area of the premises specified in the application.

(7) A pharmacy contractor participating in arrangements for the provision of hypodermic needle exchange services shall maintain records in relation to those services which shall include–

(a) the number of hypodermic needles and syringes issued by such pharmacy contractor;

(b) an estimate of the number of used hypodermic needles and syringes received by such pharmacy contractor for disposal; and

(c) the number of persons to whom such pharmacy contractor has supplied hypodermic needles and syringes.

(8) A pharmacy contractor may at any time give notice in writing to the Board that such pharmacy contractor wishes to cease to be included in arrangements for the provision of hypodermic needle exchange services either immediately or at such time as may be specified in the notice.

(9) The Board may at any time, by giving notice in writing to a pharmacy contractor, terminate such pharmacy contractor's involvement in arrangements for the provision of hypodermic needle exchange services either immediately or with effect from such date as may be specified in the notice.

Additional professional services

4.—(1) A pharmacy contractor may undertake to provide additional professional services.

(2) In these Regulations "additional professional services" means–

(a) the setting aside in a pharmacy of an area for the display of health education material;

(b) the provision to the public of advice and counselling on medicines and appliances;

(c) the undertaking of clinical audits where clinical audit means the systematic and critical analysis of the quality of clinical care; and

(d) the publication by a pharmacy contractor of a practice leaflet which shall–

(i) include the name, address and telephone number of the pharmacy and the hours in each day of the week during which that pharmacy contractor provides pharmaceutical services from those premises;

(ii) detail the arrangements for dealing with after-hours and other urgent requirements from or in relation to that pharmacy;

(iii) state that National Health Service prescriptions are dispensed and which other National Health Service pharmaceutical services are provided; and

(iv) state that a pharmacist is available to advise and answer questions about medicines and the treatment of common ailments.

Pharmaceutical list

5.—(1) The Board shall prepare a list to be called "the pharmaceutical list" of, subject to the provisions of regulation 26 (practitioners subject to inquiry) of the National Health Service (Tribunal) (Scotland) Regulations 2004(**31**), the names of persons, other than doctors and dentists, who undertake to provide pharmaceutical services and of the addresses of the premises within the Board's area from which these persons undertake to provide such services. The said list shall also state the nature of the pharmaceutical services to be provided, and the days and hours during which the premises are open, and show pharmacists as a separate category of persons within that list.

(2) A person (hereinafter referred to in this regulation as an "applicant")–

(a) who wishes to be included in the pharmaceutical list for the provision of pharmaceutical services; or

(b) whose name is already included in the pharmaceutical list, but who intends–

(i) to open within the Board's area additional premises from which to provide pharmaceutical services, or

(ii) to relocate within the Board's area the premises from which the applicant provides pharmaceutical services

shall apply to the Board in accordance with whichever version of Form A set out in Schedule 2 is appropriate or, in the case of an application to which the applicant proposes that paragraph (4) should apply, Form A(MR) set out in that Schedule.

(3) Where an application is made and–

(**31**) S.S.I. 2004/38. Regulation 26 was amended by S.S.I. 2004/122 and 2006/122.

(a) the applicant intends to provide the same pharmaceutical services from premises from which, at the time of the application, another person whose name is included in the pharmaceutical list provides those services, in place of that person; and

(b) the condition specified in paragraph (5) is fulfilled,

the Board shall grant the application.

(4) Where an application is made and–

(a) the applicant intends to relocate to new premises, within the neighbourhood in which the applicant provides pharmaceutical services, from the premises already listed in relation to such applicant, and to provide from those new premises the same pharmaceutical services which such applicant is listed as providing from the applicant's existing premises;

(b) the Board is satisfied that the relocation is a minor relocation; and

(c) the condition specified in paragraph (5) is fulfilled,

the Board shall grant the application.

(5) The condition referred to in paragraphs (3)(b) and (4)(c) is that in either case the provision of the particular pharmaceutical services by the applicant will not be interrupted, except for any period during which, in terms of any scheme made under regulation 11(1) that applies to the applicant, or any such longer period as the Board may for good cause allow, the provision of such services is not required.

(6) In this regulation the reference to a minor relocation is to one where there will be no significant change in the neighbourhood population in respect of which pharmaceutical services are provided by the applicant and other circumstances are such that there will be no appreciable effect on the pharmaceutical services provided by the applicant or any other person whose name is included in the pharmaceutical list of the Board.

(7) Before satisfying itself that a relocation is a minor relocation the Board shall seek and take into account the views of the Area Pharmaceutical Committee and of the most senior pharmaceutical adviser, or equivalent, of the Board.

(8) In the case of an application to which paragraph (4)(a) applies, where the Board is not satisfied that the relocation is a minor relocation, it shall not grant the application but shall notify the applicant in writing of its decision and of its reasons.

(9) Nothing in this regulation shall preclude or prevent an applicant from making an application in accordance with Form A or Form A(MR) in circumstances where the applicant considers that paragraph (4) may apply to such an application.

(10) An application made in any case other than one to which paragraph (3) or (4) applies shall be granted by the Board, after the procedures set out in Schedule 3 have been followed, only if it is satisfied that the provision of pharmaceutical services at the premises named in the application is necessary or desirable in order to secure adequate provision of pharmaceutical services in the neighbourhood in which the premises are located by persons whose names are included in the pharmaceutical list.

(11) Where an application is granted, it shall be notified in accordance with whichever version of Form C set out in Schedule 2 is appropriate.

(12) Where an application is granted in accordance with paragraph (10), it shall be competent for the Board to grant it only in respect of some of the pharmaceutical services specified in that application.

(13) An application, in any case other than one to which paragraph (4) applies, which is made by a person who qualified as a pharmacist in an EEA State other than the United Kingdom, or in Switzerland, shall not be granted unless the applicant satisfies the Board that the applicant has the knowledge of English, which, in the interests of the applicant and persons making use of the services

to which the application relates, is necessary for the provision of pharmaceutical services in the Board's area.

(14) Where an application is granted, the Board shall make the relevant entries in the pharmaceutical list only after the expiry of the period within which an appeal against the decision to grant the application might be intimated or the conclusion of all the appeal procedures, whichever is appropriate.

Temporary relocations and additional premises

6.—(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.

Effect to be given to corresponding decisions in England, Wales and Northern Ireland

7.—(1) A Health Board shall not include the name of any person in its pharmaceutical list, and shall remove the name of any person from its pharmaceutical list, if any decision has been made in England, Wales or Northern Ireland to deal with that person in any way which corresponds (whether or not exactly) with a way in which a person may be dealt with under section 29B(2)(**32**) , 30(2) or (5)(**33**) (except a decision to remove a disqualification or conditional disqualification) or 32B(1)(**34**) of the Act, for so long as that decision is in force.

(2) Where any corresponding decision is made in England, Wales or Northern Ireland by an equivalent body that–

(a) a person is to be included in an equivalent list subject to conditions;

(b) a person is to be removed from an equivalent list contingent on conditions;

(c) a person is to be disqualified from an equivalent list subject to conditions; or

(d) any conditions so imposed are varied,

a Health Board shall impose those conditions in relation to the provision by that person of pharmaceutical services in the area of the Health Board.

(**32**) Section 29B(2) was added by the 1999 Act, section 58, and amended by the Community Care and Health (Scotland) Act 2002 (asp 5), Schedule 2, paragraph 2, the 2004 Act, Schedule 1, paragraph 1, and the 2005 Act, section 26(4) and schedule 3.
(**33**) Section 30(2) and (5) was substituted by the 1999 Act, section 58, and amended by the 2005 Act, Schedule 3.
(**34**) Section 32B(1) was inserted by the 1999 Act, section 65 and Schedule 4, paragraph 52, and amended by the 2005 Act, schedule 3.

(3) The Health Board may make such modifications of the conditions referred to in paragraph (2) as it considers necessary for them to have the like effect in relation to Scotland as they do in relation to England, Wales or (as the case may be) Northern Ireland, but only if the Health Board has previously given the person concerned written notice of the proposed modifications and an opportunity to make representations about them.

Provisional pharmaceutical list

8.—(1) The Board may also in accordance with this regulation prepare a list, to be called "the provisional pharmaceutical list" in which there shall be included, subject to the provisions of regulation 26 (practitioners subject to inquiry) of the National Health Service (Tribunal) (Scotland) Regulations 2004, the name of any person, other than a doctor or dentist, who undertakes provisionally to provide pharmaceutical services. The provisional pharmaceutical list shall state the particulars required under regulation 5(1) in relation to any such person and also the date ("the provisional date") from which such person undertakes to provide pharmaceutical services at the premises specified in an application under regulation 5(2).

(2) Where in any application under paragraph (2) of regulation 5 to which paragraph (4) or (10) of that regulation applies–

(a) any one or more of the statements in paragraph (2)(b) of Form A or, as the case may be, Form A(MR), is negative; and

(b) the Board is satisfied on the basis of such information as may be submitted with the application that the applicant intends to commence business at the premises specified in the application in the event of the applicant's name being included in the pharmaceutical list,

the Board, in the case of an application to which paragraph (10) of regulation 5 applies, shall notify and otherwise deal with the application in accordance with that paragraph and Schedule 3 or, in the case of an application to which paragraph (4) of that regulation applies, shall deal with it in accordance with that paragraph and in either case where the Board grants the application the Board may include the name of the applicant in the provisional pharmaceutical list for its area.

(3) Where an application is determined by the inclusion of the name of the applicant in the provisional pharmaceutical list, the Board shall give notification of the decision to the applicant in Form D set out in Schedule 2, and in this regulation any reference to "the date of inclusion" is to the date of inclusion in the provisional pharmaceutical list as stated in Form D.

(4) Subject to paragraph (5) the applicant shall, as soon as reasonably practicable after the date of inclusion and in any event not later than either–

(a) the date six months after the date of inclusion, or

(b) if earlier, the provisional date,

submit Form B set out in Schedule 2 with any information required but not given in paragraph 2(b) of Form A or, as the case may be, Form A(MR), and on receipt of such information the Board shall include the name of the applicant in the pharmaceutical list and remove it from the provisional pharmaceutical list.

(5) Where a person whose name has been included in the provisional pharmaceutical list applies in writing to the Board not later than twenty eight days before the date by which, in terms of paragraph (4) above, the applicant is required to submit Form B, that the applicant wishes the Board to extend the period for submission of that Form and the Board is satisfied that, due to circumstances outwith that person's control and which could not reasonably have been anticipated at the date of the application, there is no reasonable prospect of such person being able to submit that Form by that date, the Board may extend the period for submission of Form B by a further period not exceeding nine months.

(6) Where an applicant, whose name is included in the provisional pharmaceutical list, has not submitted Form B in accordance with paragraphs (4) or (5), the applicant's name shall be removed from the provisional pharmaceutical list.

Removal from and amendment to pharmaceutical list

9.—(1) Where the Board determines in accordance with paragraph (3) that a person whose name has been included for the preceding six months in the pharmaceutical list has not during that period provided pharmaceutical services the Board shall remove that person's name from the said list.

(2) A period during which the person was suspended by direction of the Tribunal does not count towards the period of six months referred to in paragraph (1).

(3) Where a Board determines in accordance with paragraph (4) that the supply of equipment necessary to provide domiciliary oxygen therapy service is no longer required, either in total or in part, and this service or part thereof has not been provided for the preceding six months the Board may cancel or amend the contract to provide the domiciliary oxygen therapy service contracted for.

(4) Before making a determination under paragraphs (1) or (3), the Board shall–

(a) give the person not less than 28 days' notice in writing of its intention so to do;

(b) afford the person an opportunity of making written representations to the Board; and

(c) consult the Area Pharmaceutical Committee.

(5) Nothing in paragraphs (1) and (3) shall–

(a) prejudice the right of a person to apply to be included again in the pharmaceutical list; or

(b) prevent a person from applying to increase the supply of equipment for domiciliary oxygen therapy service already provided; or

(c) affect a person who is performing a period of relevant service and in such a case no removal under paragraphs (1) or (3) shall be effected in respect of any such person until six months after such person has completed that service.

Transitional Arrangements

10. Where, before the date these Regulations come into force any application is made, any action is commenced or any decision is pending by a Board, the Agency or the National Appeal Panel under the National Health Service (Pharmaceutical Services) (Scotland) Regulations 1995(**35**), the provisions of those Regulations shall, notwithstanding regulation 17 (revocations) continue to apply on or after that date in respect of any such action or decision.

Schemes for securing proper pharmaceutical service

11.—(1) The Board, after consultation with the Area Pharmaceutical Committee, shall prepare a scheme for securing that one or more places of business on the pharmaceutical list in the area of the Board shall at all reasonable times be open. The scheme shall specify the days and hours during which such places shall be open, and the arrangements for the dispensing of medicines required urgently at other times.

(2) The provisions of schemes prepared under paragraph (1) shall be subject to the approval of the Scottish Ministers.

(**35**) S.I. 1995/414, 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.

(3) In the event of the Board and the Area Pharmaceutical Committee failing to agree on any provision of a scheme to be prepared under paragraph (1), the matter shall be referred to the Scottish Ministers, whose determination shall be final.

(4) Where the Board after consultation with the Area Pharmaceutical Committee, amends the provisions of a scheme approved under paragraph (2), the Area Pharmaceutical Committee or any person whose name is included in the pharmaceutical list may appeal in respect of any such amendment, and any such appeal–

(a) shall be made in writing and received by the Board within 21 days from the date on which notification of that amendment was published; and

(b) may be determined by the Scottish Ministers; or

(c) if the Scottish Ministers so decide, be determined in accordance with the procedures set out in paragraph 5(3) to (5) of Schedule 3 and paragraphs 9 to 15 of Schedule 4.

(5) 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.

Payments to pharmacy contractors and standards of drugs and appliances

12.—(1) The Scottish Ministers shall after consultation with an organisation which is, in their opinion, representative of the general body of pharmacy contractors cause to be prepared a statement (in these Regulations referred to as "the Drug Tariff") which they may after such consultation amend from time to time and which (subject to paragraph (2)) shall include–

(a) the prices on the basis of which the payment for specified drugs (being drugs commonly prescribed) and appliances is to be calculated;

(b) the method of calculating the payment for drugs not specified in the Drug Tariff;

(c) the dispensing fees or other sums payable in respect of the supply of drugs and appliances and of additional professional services;

(d) arrangements for claiming fees, allowances and remuneration in connection with the making and implementation of arrangements for the provision of pharmaceutical services;

(e) the standards of quality for drugs;

(f) the list of appliances approved by the Scottish Ministers for the purposes of section 27 of the Act, the specifications for such appliances and, in the case of a restricted availability appliance, the categories of persons for whom or the purposes for which the appliance is approved;

(g) the method by which a claim may be made for compensation for financial loss in respect of oxygen equipment;

(h) the list of chemical reagents approved by the Scottish Ministers for the purpose of section 27 of the Act and the specification for such chemical reagents; and

(i) the fees, allowances and remuneration payable for the provision of such directed services as may be specified.

(2) The Drug Tariff may state in respect of any specified fee falling within paragraph (1)(c) or (i), or any other specified fee, allowance or other remuneration in respect of the provision of pharmaceutical services by pharmacy contractors included in the pharmaceutical list of a Board, that the determining authority for that fee, allowance or other remuneration for those pharmacy contractors is the Board, and in such a case paragraphs (3), (4) and (5) shall apply(**36**).

(**36**) "The Drug Tariff is published monthly as a web-based version at http://www.isdscotland.org/isd/2245.html. An annual hard copy is published on 1st April each year. To be added to the mailing list for the hard copy distribution, email: evadis@isd.csa.scot.nhs.uk".

(3) The Board shall consult such body as it considers representative of pharmacy contractors in its area before making any determination by virtue of paragraph (2).

(4) A determination made by the Board by virtue of paragraph (2) shall include the arrangements for claiming the specified fees, allowances or other remuneration and may provide that the pharmacy contractor requires to have prior authority from the Board to provide a specified service and associated drugs.

(5) A determination made by the Board by virtue of paragraph (2) shall be notified in writing to all pharmacy contractors included in its pharmaceutical list.

Payments to pharmacy contractors in respect of suspended pharmacists

13.—(1) The Board shall make payments to a pharmacy contractor (if a pharmacist), or to a pharmacy contractor in respect of a pharmacist engaged by that pharmacy contractor, who is suspended by direction of the Tribunal in accordance with the determination of the Scottish Ministers in relation to such payments.

(2) The Scottish Ministers shall make the determination in accordance with paragraph (1) after consultation with the organisation referred to in regulation 12(1), and it shall be published with the Drug Tariff.

(3) The determination may be amended from time to time by the Scottish Ministers, after consultation with the organisation referred to in paragraph (2), and any amendments shall also be published with the Drug Tariff.

(4) Subject to paragraph (5), the determination of the Scottish Ministers shall be such as to secure that, as far as reasonably practicable, and after making adjustments for any reduction in expenses, the suspended pharmacist receives payments at a rate corresponding to the suspended pharmacist's remuneration under the Drug Tariff (but excluding any payments made by virtue of regulation 12(1)(g)) during the 12 months ending with the direction for suspension by the Tribunal.

(5) The determination of the Scottish Ministers may include provision that payments in accordance with the determination are not to exceed a specified amount in any specified period.

Application for pharmaceutical services

14. An application to a pharmacy contractor for pharmaceutical services may be made (other than by the pharmacist concerned) on behalf of any person who is incapable of requesting pharmaceutical services themself on account of sickness or infirmity by any duly authorised person.

Publication of particulars

15.—(1) The Board shall make available for inspection at its offices copies of–

(a) the pharmaceutical list;

(b) the terms of service for pharmacists and pharmacy contractors;

(c) the Drug Tariff;

(d) any schemes made under regulation 11 and shall keep them revised and up-to-date; and

(e) determinations made by the Board by virtue of regulation 13(2).

(2) The Board may make any of the documents described in paragraph (1) of this regulation available for inspection at such other places in its area as appear convenient for informing all persons interested, or may publish at such places a notice of the places and times at which copies of any of those documents may be inspected.

(3) The Board shall send a copy of the pharmaceutical list to the area medical, dental and pharmaceutical committees, and shall within fourteen days of any alteration in the pharmaceutical list inform each of them of such alteration.

(4) The Board shall send a copy of the pharmaceutical list to all pharmacy contractors on the list.

(5) Paragraph (3) shall not apply to alterations in a pharmaceutical list made by a Board in terms of regulation 6(2).

Service of documents

16. Except where expressly provided to the contrary, any document which is required or authorised to be given or sent to a person or body under these Regulations (including the terms of service) may be given or sent by delivering it to that person, or in the case of a body, to the secretary or general manager of that body or by sending it to that person, or in the case of a body, to the secretary or general manager of that body at that person's usual or last known address.

Revocations

17. The Regulations specified in column (1) of Schedule 5 are revoked to the extent specified in column (3) of that Schedule.

Consequential amendments

18. The provisions listed in Schedule 6 are amended as specified in that Schedule.

St Andrew's House,
Edinburgh
14th May 2009

SHONA ROBISON
Authorised to sign by the Scottish Ministers