STATUTORY INSTRUMENTS

2004 No. 922

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical Services) (Amendment) Regulations 2004

Made - - - - 25th March 2004

Laid before Parliament 26th March 2004

Coming into force - - 1st April 2004

The Secretary of State for Health, in exercise of the powers conferred upon him by sections 41, 42, 43 and 126(4) and (5) of the National Health Service Act 1977(a) and of all other powers enabling him in that behalf, hereby makes the following Regulations:

Citation, commencement, application and interpretation

- 1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services) (Amendment) Regulations 2004 and shall come into force on 1st April 2004.
- (2) These Regulations shall apply to England only(b).
- (3) The National Health Service (Pharmaceutical Services) Regulations 1992(c) ("the Principal Regulations") are amended in accordance with the provisions of these Regulations.

Amendment of regulation 2

- **2.**—(1) In regulation 2(1) (interpretation)—
 - (a) for the definition of "appropriate non-proprietary name" substitute—
- (a) 1977 c.49; Section 41 was substituted by the Health and Social Care Act 2001 (c.15) ("the 2001 Act"), section 42(1), and amended by the National Health Service Reform and Healthcare Professions Act 2002 (c.17) ("the 2002 Act"), Schedule 2, paragraph 13; and by the Health and Social Care (Community Health and Standards) Act 2003 (c.43) ("the 2003 Act"). Section 42 was substituted by the National Health Service (Amendment) Act 1986 (c.66), section 3(1); extended by the Health and Medicines Act 1988 (c.49), section 17; and amended by S.I. 1987/2202, article 4; by the National Health Service and Community Care Act 1990 (c.19) ("the 1990 Act"), section 12(3); by the Health Authorities Act 1995 (c.17) ("the 1995 Act"), Schedule 1, paragraph 30; by the Pharmacists (Fitness to Practice) Act 1997 (c.19), Schedule, paragraph 6; by the 2001 Act, sections 20(6), 23(5), 40(3), 43(2), (3) and (4) and by Schedule 6 Part 1; and by the 2002 Act, Schedule 2, paragraph 16. Section 43 was amended by the 1995 Act, Schedule 1, paragraph 31; by the Health Services Act 1980 (c.53), section 21(2); by the National Health Service (Primary Care) Act 1997 (c.46), section 29(1) and Schedule 2, paragraph 14; by the 1990 Act, Schedule 9, paragraph 18(2); by the 2001 Act, sections 20(7), 42(2) and 43(5); by the 2002 Act, Schedule 2, paragraph 17; and by the 2003 Act Schedule 11, paragraph 19. Section 126(5) was inserted by the 1990 Act, section 65(2); and amended by the 2001 Act, Schedule 5, paragraph 5(13)(d). See section 128(1) of the National Health Service Act 1977 as amended by the 1990 Act, section 26(2)(g) and (i), for the definitions of "prescribed" and "regulations".
- (b) As regards Wales, the functions of the Secretary of State under sections 41, 42, 43 and 126 of the 1977 Act were transferred to the National Assembly for Wales under S.I. 1999/672, article 2 and Schedule 1, as amended by the 1999 Act, section 66(5) and as read with section 40(1) of the 2002 Act.
- (c) S.I. 1992/662. Relevant amending instruments are 1994/2402, 1996/698, 1998/681, 1998/2224, 1999/696, 2000/593, 2001/2888, 2002/551, 2002/888, 2002/2016, 2002/2469, 2002/2861, 2002/3135, 2003/699, 2003/1084.

""appropriate non-proprietary name" means a non-proprietary name which is not mentioned in Schedule 1 to the Prescription of Drugs Regulations or, except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied, in Schedule 2 to the Prescription of Drugs Regulations;";

(b) for the definition of "independent nurse prescriber" substitute—

""independent nurse prescriber" means a person—

- (a) who is registered in the Nursing and Midwifery Register, and
- (b) in respect of whom an annotation signifying that he is qualified to order drugs and appliances from—
 - (i) the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVIIB(i) of the Drug Tariff, or
 - (ii) the Nurse Prescribers' Extended Formulary in Part XVIIB(ii) of the Drug Tariff.

is also recorded in that register;";

(c) for the definition of "Local Medical Committee" substitute—

"Local Medical Committee" means a committee recognised under section 45A of the Act;";

(d) for the definition of "patient" substitute—

""patient" in relation to a GMS contract has the same meaning as in regulation 2 of the GMS Regulations (interpretation), in relation to a PMS agreement has the same meaning as in regulation 2 of the PMS Regulations (interpretation), and in relation to arrangements made under section 16CC of the Act(a) means any person to whom the contractor has agreed or is required to provide services under those arrangements;";

- (e) in the definition of "prescription form", for the words "and issued by a doctor, dentist, supplementary prescriber or independent nurse prescriber" substitute the words "and issued by a prescriber or a dentist";
- (f) for the definition of "Remission of Charges Regulations" substitute—

""Remission of Charges Regulations" means the National Health Services (Travel Expenses and Remission of Charges) Regulations 2003(b)";

(g) for the definition of "repeatable prescription" substitute—

""repeatable prescription" means a prescription contained in a form provided by a Primary Care Trust and issued by a repeatable prescriber to enable a person to obtain pharmaceutical services or local pharmaceutical services, which is in the format specified in Part 1 of Schedule 1 to the GMS Regulations, and which—

- (a) is generated by a computer but signed by a repeatable prescriber; and
- (b) indicates that the drugs or appliances ordered on that form may be provided more than once, and specifies the number of occasions on which they may be provided;" .
- (h) for the definition of "Scheduled drug" substitute—

""Scheduled drug" means a drug or other substance specified in Schedule 1 to the Prescription of Drugs Regulations, or except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied, Schedule 2 to the Prescription of Drugs Regulations;";

(i) for the definition of "supplementary prescriber" substitute—

""supplementary prescriber" means a person—

(a) whose name is registered in—

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⁽a) Section 16CC was inserted into the Act by section 174 of the 2003 Act.

⁽b) S.I. 2003/2382

- (i) the Nursing and Midwifery Register,
- (ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954(a), or
- (iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(b), and
- (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs and appliances as a supplementary prescriber.";
- (j) omit the following definitions—
- "Community Health Council",
- "doctor's list",
- "doctors' terms of service",
- "medical list",
- "Medical Regulations",
- "personal medical services"
- "pilot scheme", and
- "pilot scheme provider";
- (k) insert the following definitions at the appropriate place in alphabetical order—
 - ""the 2003 Act" means the Health and Social Care (Community Health and Standards) Act 2003(c);",
 - ""GMS contract" means a general medical services contract and "GMS contractor" shall be interpreted accordingly;",
 - ""the GMS Regulations" means the National Health Service (General Medical Services Contracts) Regulations 2004(d);",
 - ""medical performers list" means a list of doctors prepared and published pursuant to regulations 3(1) of the National Health Service (Performers Lists) Regulations 2004(e);
 - ""Nursing and Midwifery Register" means the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001(f);",
 - ""patient list" means a list of a patients kept by a Primary Care Trust—
 - (i) in respect of a GMS contractor , in accordance with paragraph 14 of Schedule 6 to the GMS Regulations, or
 - (ii) in respect of a PMS contractor, in accordance with paragraph 13 of Schedule 5 to the PMS Regulations;";
 - ""PMS agreement" means an agreement made under section 28C of the Act (g);",
 - ""PMS contractor" means a party to a PMS agreement;",
 - ""the PMS Regulations" means the National Health Service (Personal Medical Services Agreements) Regulations 2004(h);",

⁽**a**) c.61

⁽b) S.I.1976/1213 (N.I.22).

⁽**c**) c.43.

⁽**d**) S.I. 2004/291

⁽e) S.I. 2004/585

⁽**f**) S.I. 2002/253

⁽g) Section 28C was inserted into the Act by section 21(1) of the National Health Service (Primary Care) Act 1997 (c.46) and amended by section 4(3), Schedule 3 Part 1 paragraphs 1, 7(1) and 2(a) of the National Health Service Reform and Health Care Professions Act 2002(c.17); section 40, Schedule 5 Part 1, paragraph 11(1) and (4) of the Health and Social Care Act 2001(c.15) sections 184, Schedule 11 paragraphs 7 and 14 of the 2003 Act

⁽**h**) S.I. 2004/627

""Patients' Forum" means a body established under section 15(1) of the National Health Service Reform and Health Care Professions Act 2002 (a)",

""prescriber" means a doctor, an independent nurse prescriber or a supplementary prescriber;",

""the Prescription of Drugs Regulations" means the National Health Service (General Medical Services Contracts)(Prescription of Drugs etc.) Regulations 2004(b);",

""relevant GMS contractor", in relation to any doctor means the GMS contractor by whom the doctor is employed or engaged;",

""relevant PMS contractor", in relation to any doctor means the PMS contractor by whom the doctor is employed or engaged;",

""relevant patient list" means, in relation to a doctor who is (or is a legal and beneficial shareholder in a company which is) a GMS contractor or a PMS contractor, the patient list for that contractor or, where he is not a contractor, means the patient list for the GMS contractor or PMS contractor by whom he is engaged or employed;",

""relevant register" means—

- (a) in relation to a nurse, the Nursing and Midwifery Register, and
- (b) in relation to a pharmacist, the register maintained in pursuance of section 2(1) of the Pharmacy Act 1954 (the registers and registration) or the register maintained in pursuance of articles 6 (the registers) and 9 (the registrar) of the Pharmacy (Northern Ireland) Order 1976;";

""repeatable prescriber" means a prescriber who is-

- (a) a GMS contractor who provides repeatable prescribing services under the terms of its contract which give effect to paragraph 40 of Schedule 6 to the GMS Regulations;
- (b) a PMS contractor who provides repeatable prescribing services under the terms of its agreement which give effect to paragraph 39 of Schedule 5 to the PMS Regulations; or
- (c) employed or engaged by a GMS contractor who provides repeatable prescribing services under the terms of a contract which give effect to paragraph 40 of Schedule 6 to the GMS Regulations or by a PMS contractor who provides repeatable prescribing services under the terms of an agreement which give effect to paragraph 39 of Schedule 5 to the PMS Regulations;".
- (2) For regulation 2(1B) substitute—
 - "(1B) In these Regulations—
 - (a) the term "pharmaceutical services", in relation to a doctor, means those services referred to in regulation 20; and
 - (b) the term "dispensing services", in relation to a doctor or to a GMS contractor or a PMS contractor means, any corresponding service provided, not as pharmaceutical services, but under the terms of a GMS contract which give effect to paragraphs 47 to 51 of Schedule 6 to the GMS Regulations or under the terms of a PMS agreement which give effect to paragraphs 45 to 51 of Schedule 5 to the PMS Regulations."
- (3) After regulation 2(4) add—
 - "(5) For as long as there are in existence—
 - (a) contracts entered into under article 13 of the General Medical Services Transitional and Consequential Provisions Order 2004(c) ("default contracts") in respect of

⁽a) c.17. Section 15(1) was amended by section 31(2)(a) and Schedule 14, part 1 of the Health and Social Care (Community Health and Standards Act 2003 (c.43)

⁽**b**) S.I. 2004/629

⁽c) S.I. 2004/433

- such contracts any reference to a GMS contract shall be read as including a reference to a contract entered into under that article and any reference to a term of a GMS contract shall be read as including a reference to the equivalent term in the default contract;
- (b) transitional agreements as defined in article 1(4) of the General Medical Services and Personal Medical Services Transitional and Consequential Provisions Order 2004(a), any reference in these Regulations to a PMS agreement shall be read as including a reference to any equivalent term in the transitional agreement.".

Omission of regulation 2A

3. Regulation 2A is omitted.

Amendment of regulation 5

4. In regulation 5(1)(e) (notification of applications), for the words "Community Health Council" substitute the words "Patients' Forum".

Amendment of regulation 6

- **5.** For regulation 6(6) (determination of applications) substitute—
 - "(6) No person—
 - (a) who provides or assists in providing pharmaceutical services under Part II of the Act; or
 - (b) who holds a GMS contract, or is a legal and beneficial shareholder, director or company secretary of a company which holds a GMS contract, or is employed or engaged by a person who holds such a contract; or
 - (c) who is a PMS contractor, or is a legal and beneficial shareholder, director or company secretary of a company which is a party to a PMS agreement, or is employed or engaged by a PMS contractor; or
 - (d) who provides primary medical services pursuant to arrangements made under section 16CC(2)(b) of the Act, or is a legal and beneficial shareholder, director or company secretary of a company which provides primary medical services pursuant to such arrangements, or is employed or engaged by such a provider; or
 - (e) who is a party (other than a Primary Care Trust) to a pharmacy pilot scheme, or a director, officer or employee of such a person, or who provides or assists in providing local pharmaceutical services under a pharmacy pilot scheme,

shall take part in any decision under this regulation.".

Amendment of regulation 7

6. In regulation 7(1)(a)(vi) (notification of decisions) for the words "Community Health Council" substitute the words "Patients' Forum".

Amendment of regulation 9

- 7.—(1) In regulation 9(5) (determination of controlled locality), for the word "doctor" insert "provider of primary medical services under Part I of the Act".
- (2) For regulation 9(6) substitute—
 - "(6) Where the Primary Care Trust determines that any area or part of an area is or is not rural in character, it shall consider whether the provision of primary medical services by

any provider of primary medical services, or pharmaceutical services by any chemist, or local pharmaceutical services by any LPS chemist, is likely to be adversely affected in consequence of that determination.".

(3) For regulation 9(7) substitute—

"(7) Where the Primary Care Trust considers that the provision of primary medical services by any doctor, GMS contractor or PMS contractor, or pharmaceutical services by any chemist, or local pharmaceutical services by any LPS chemist is likely to be adversely affected in consequence of a determination under paragraph (4), it may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 for the provision by a doctor of pharmaceutical services to his patients."

Amendment of regulation 11

- **8.**—(1) In regulation 11(2)(a) (applications for inclusion in pharmaceutical lists in respect of controlled localities)—
 - (i) for the words "one mile", substitute "1.6 kilometres", and
 - (ii) after the words "pharmaceutical services" add "or for whom a GMS contractor or PMS contractor provides dispensing services".
 - (2) In regulation 11(3), for the words "one mile" substitute "1.6 kilometres".

Amendment of regulation 12

- **9.**—(1) For regulation 12(1)(c) (determination of applications in respect of controlled localities) substitute—
 - "(c) any person who is a provider of primary medical services within the area of the Primary Care Trust or whose name is included in the pharmaceutical list [or dispensing doctor list] of the Primary Care Trust, or who provides local pharmaceutical services under a pharmacy pilot scheme entered into by that Primary Care Trust, who, in its opinion, might be affected by the grant of the application;".
- (2) For regulation 12(1)(d)(i) substitute—
 - "(i) in whose area a person provides primary medical services, who in the opinion of the Primary Care Trust might be so affected, or
 - (ia) in whose pharmaceutical list or dispensing doctor list is included the name of a person who, in the opinion of the Primary Care Trust, might be so affected, or".
- (3) In regulation 12(1)(e) for the words "Community Health Council" substitute the words "Patients' Forum".
 - (4) For regulation 12(2)(c) substitute—
 - "(c) any person who is a provider of primary medical services or whose name is included in the pharmaceutical list, or who provides local pharmaceutical services under a pharmacy pilot scheme entered into by that Primary Care Trust, who might, in its opinion, be affected by the grant of the application."
 - (5) Regulation 12(2A) is omitted.
 - (6) For regulation 12(10) substitute—
 - "(10) No person—
 - (a) who provides or assists in providing pharmaceutical services under Part II of the Act; or
 - (b) who is a GMS contractor, or is a legal and beneficial shareholder, director or company secretary of a company which is a GMS contractor, or is employed or engaged by a GMS contractor; or

- (c) who is a PMS contractor, or is a legal and beneficial shareholder, director or company secretary of a company which is a PMS contractor, or is employed or engaged by a PMS contractor; or
- (d) who provides primary medical services pursuant to arrangements made under section 16CC(2)(b) of the Act, or is a legal and beneficial shareholder, director or company secretary of a company which provides primary medical services pursuant to such arrangements, or is employed or engaged by such a provider; or
- (e) who is a party (other than a Primary Care Trust) to a pharmacy pilot scheme, or a director, officer or employee of such a person, or who provides or assists in providing local pharmaceutical services under a pharmacy pilot scheme,

shall take part in any decision under this regulation.".

- (7) In regulation 12(13)(a), for the words "general medical services, personal medical services" substitute "primary medical services under Part I of the Act".
 - (8) In regulation 12(13)(b)(ii), for the words "one mile", substitute "1.6 kilometres".
- (9) In regulation 12(13)(c), for the words "general medical services, personal medical services" substitute "primary medical services"
- (10) In regulation 12(14), for the words "general medical services or personal medical services by any doctor" substitute "primary medical services by any provider of such services".
 - (11) For regulation 12(15) substitute—
 - "(15) Where the Primary Care Trust considers that the provision of primary medical services by any provider of such services or pharmaceutical services by any chemist or local pharmaceutical services by any LPS chemist is likely to be adversely affected in consequence of a grant under paragraph (14), it may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 for the provision by a doctor of pharmaceutical services to patients on the relevant patient list.".
 - (12) In regulation 12(17)(b)(i), for the words "one mile" substitute "1.6 kilometres".

Amendment of regulation 13

- **10.**—(1) For regulation 13(2)(a)(ii) (appeals in connection with determination under regulation 12) substitute—
 - " (ii) any person who-
 - (aa) provides primary medical services within the area of the Primary Care Trust, or any other Primary Care Trust to which a copy of the application was sent under regulation 12(1)(d),
 - (bb) whose name is included in the pharmaceutical list [or dispensing doctor list] of the Primary Care Trust, or any other Primary Care Trust to which a copy of the application was sent under regulation 12(1)(d), or".
- (2) Regulation 13(2)(a)(iii) is omitted.
- (3) In regulation 13(13)(b), for the words "his patients" substitute "patients on the relevant patient list".

Amendment of regulation 16B

- 11.—(1) For regulation 16B(2) (repeat dispensing services) substitute—
 - "(2) The conditions referred to in paragraph (1)(a) are that the chemist—
 - (a) is not a supplier of appliances only; and
 - (b) is included in the pharmaceutical list of a Primary Care Trust specified in Schedule 3A.".
- (2) For regulation 16B(4)(b) substitute—

"(b) at least ten days after the date on which the notification specified in paragraph (3) is given.".

Omission of regulation 19

12. Regulation 19 (provision of pharmaceutical services for immediate treatment or personal administration) is omitted.

Amendment of regulation 20

- **13.** For regulation 20 (arrangements for provision of pharmaceutical services by doctors) substitute—
 - "20.—(1) Where a patient—
 - (a) satisfies a Primary Care Trust that he would have serious difficulty in obtaining any necessary drugs or appliances from a pharmacy by reason of distance or inadequacy of means of communication; or
 - (b) is resident in a controlled locality, at a distance of more than 1.6 kilometres from any pharmacy, and one of the conditions specified in paragraph (3) is satisfied in his case,

he may at any time request in writing a doctor who falls within paragraph (2) to provide him with pharmaceutical services.

- (2) A doctor falls within this paragraph if he is—
 - (a) the GMS contractor or PMS contractor, or
- (b) engaged or employed by the GMS contractor or PMS contractor on whose patient list the patient making the request is included.
 - (3) The conditions referred to in paragraph (1)(b) are—
 - (a) that—
 - (i) there is in effect an outline consent granted to that doctor or to another doctor who is a party to the GMS contract or PMS agreement concerned, or is engaged or employed by the GMS contractor or PMS contractor concerned in respect of the area in which the patient resides; and
 - (ii) any conditions imposed under regulation 12(15) or regulation 13(13)(b) in connection with that grant are such as to permit arrangements to be made under this regulation for the provision of pharmaceutical services by that doctor to the patient; or
 - (b) immediately before these Regulations came into force arrangements or requirements were in effect under regulations revoked by these Regulations for that doctor or his partner or any previous doctor in his practice to provide drugs or appliances to patients, and the patient—
 - (i) has not previously been included in a patient list,
 - (ii) has changed his address from that last notified to the Primary Care Trust, or
 - (iii) has not changed his address but, immediately before his acceptance as a patient by that doctor, was being provided with pharmaceutical services by a doctor pursuant to an arrangement or requirement under these Regulations.
 - (4) If a doctor so requested by a patient under paragraph (1)—
 - (a) applies to provide pharmaceutical services to the patient, and sends with his application the patient's request in writing, the Primary Care Trust shall make arrangements with him for the provision of such services by him; or
 - (b) does not so apply within 30 days, the Primary Care Trust may, subject to paragraph (6), require him to undertake such provision and shall give him notice in writing to that effect.

- (5) An arrangement made by a Primary Care Trust under paragraph (4)(a) shall—
 - (a) have effect from the date of the patient's request in writing; and
 - (b) enable that doctor, any other doctor in his practice or any doctor who subsequently joins his practice to provide pharmaceutical services for the patient so long as the arrangement remains in effect.
- (6) A Primary Care Trust shall not under paragraph (4)(b) require a doctor to provide pharmaceutical services to a person on the relevant patient list for that doctor satisfies the Primary Care Trust, or on appeal, the Secretary of State that—
 - (a) he does not normally provide pharmaceutical services under this regulation; or
 - (b) in the case of a person to whom paragraph (1)(b) applies, the person would not have serious difficulty, by reason of distance or inadequacy of means of communication, in obtaining drugs and appliances from a pharmacy.
 - (7) A Primary Care Trust shall give a doctor reasonable notice—
 - (a) that it requires him to provide pharmaceutical services to any person; or
 - (b) subject to paragraph (8), that, where a person no longer satisfies the provisions of paragraph (1), the doctor shall discontinue the provision of pharmaceutical services to that person.
 - (8) A notice under paragraph (7)(b)—
 - (a) shall be subject to any postponement or termination of arrangements for the provision of pharmaceutical services to that person by that doctor made under regulation 12(15) or 13(13); and
 - (b) shall not be given—
 - (i) pending any appeal against a decision by a Primary Care Trust to postpone the making or termination of such arrangements, or
 - (ii) where regulations 9(10) so requires.
- (9) Notwithstanding paragraph (4), where a drug or appliance is one for which a doctor is entitled to an additional payment if he provides it, he may, with the consent of the patient, instead of providing it himself, order it by issuing a prescription to the patient in accordance with paragraph 39 of Schedule 6 to the GMS Regulations.
- (10) Where under any provision of regulations revoked by, and not re-enacted in, these Regulations an arrangement or requirement for a doctor to provide drugs or appliances to a patient was in effect immediately before these Regulations came into force, that arrangement or requirement shall have effect as though made under this regulation notwithstanding that neither of the conditions specified in paragraph (3) is satisfied.
- (11) A doctor who provides pharmaceutical services to some or all of the patients on the relevant patients list in accordance with this regulation may provide any necessary pharmaceutical services to a person whom the relevant GMS or PMS contractor has accepted as a temporary resident under paragraph 16 of Schedule 6 to the GMS Regulations or under paragraph 15 of Schedule 5 to the PMS Regulations.
- (12) An appeal under paragraph (6) shall be made in writing within 30 days from the date on which notice of the decision was sent to the doctor and shall contain a concise statement of the grounds of appeal.
- (13) The Secretary of State shall, on receipt of any notice of appeal under this regulation, send a copy of that notice to the Primary Care Trust and the relevant GMS contractor or PMS contractor, and the Primary Care Trust and relevant GMS contractor and PMS contractor may, within 30 days from the date on which the Secretary of state sent a copy of the notice of appeal, make representations in writing to him.
- (14) The Secretary of State may determine an appeal pursuant to paragraph (6) in such manner as he thinks fit.
- (15) The Secretary of State shall, upon determination by him of an appeal under this regulation, give notice of his decision in writing, together with the reasons for it, to the

appellant, to the Primary Care Trust and to the relevant GMS contractor or PMS contractor.

Amendment of regulation 21

14. In regulation 21(1) (outline consent) omit the words "Health Authority or" each time they occur.

Omission of regulation 21A

15. Regulation 21A (doctors who previously performed personal medical services) is omitted.

Amendment of regulation 21B

- 16. For regulation 21B (dispensing doctor lists) substitute—
 - "21B.—(1) A Primary Care Trust shall prepare and publish a list, to be called the dispensing doctor list, of the names of those doctors authorised or required by the Primary Care Trust under regulation 20 to provide pharmaceutical services to their patients and who are actually doing so.
 - (2) The dispensing doctor list shall indicate the address of the relevant GMS contractor or PMS contractor from whose premises any doctor whose name is included performs primary medical services."

Amendment of regulation 21C

- 17. For regulation 21C substitute—
 - **"21C.** A Primary Care Trust shall remove the name of a doctor from its dispensing doctor list when—
 - (a) the doctor has died; or
 - (b) the doctor is no longer performing primary medical services within the area of the Primary Care Trust; or
 - (c) more than 12 months have elapsed since the doctor last provided pharmaceutical services pursuant to the authorisation or requirement to provide such services given by the Primary Care Trust under regulation 20."

Amendment of regulation 24

18. In regulation 24(2)(b) (claims and overpayments) after the word "where" insert ", in the case of a chemist".

Amendment of Part I(General) of Schedule 2

- **19.** In paragraph 1(2) (interpretation) of Schedule 2—
 - (a) at the end of the definition of "associated batch issue" insert "and", and for the definition of "batch issue" substitute—
 - "batch issue" means a form provided by a Primary Care Trust and issued by a prescriber at the same time as a repeatable prescription to enable a chemist to receive payment for the provision of repeat dispensing services which is in the format specified in Part 2 of Schedule 1 to the GMS Regulations, and which—
 - (a) is generated by a computer and not signed by a prescriber,
 - (b) relates to a particular repeatable prescription and contains the same date as that prescription,

- (c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the repeatable prescription may be provided, and
- (d) specifies a number denoting its place in the sequence referred to in paragraph (c)."
- (b) omit the definition of "repeatable prescribing doctor".

Amendment of Part II (terms of service for chemists) of Schedule 2

20. In Schedule 2—

- (a) in paragraph 3 (provision of pharmaceutical services)—
- (i) for subparagraph (1) substitute—
- "(1) Where any person presents on a prescription form—
 - (a) an order for drugs, not being Scheduled drugs, or appliances, not being restricted availability appliances, signed by a prescriber; or
 - (b) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, signed by, and endorsed on its face with the reference "SLS" by a prescriber; or
 - (c) an order for a restricted availability appliance, signed by and endorsed on its face with the reference "SLS" by a prescriber; or
 - (d) an order for listed drugs signed by a dentist or his deputy or assistant,

a chemist shall, with reasonable promptness, provide the drugs so ordered, and such of the appliances so ordered as he supplies in the normal course of his business.",

- (ii) for subparagraph (1ZA)(a)(a) substitute—
 - "(a) presents a repeatable prescription which contains—
 - (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971(b), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(c), signed by a repeatable prescriber,
 - (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by and endorsed on its face with the reference "SLS" by a repeatable prescriber,
 - (iii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or
 - (iv) an order for a restricted availability appliance, signed by, and endorsed on its face with the reference "SLS" by a repeatable prescriber,

and also presents and associated batch issue; or ",

- (iii) in subparagraph (1C)(d)—
 - (aa) in paragraph (a)(ii), for "regulation 3 of the Remission of Charges Regulations", substitute "regulation 5 of the Remission of Charges Regulations"; and
 - (bb) in the words following paragraph (a)(ii), for "regulation 4(2)(e), (f) or (q) of the Remission of Charges Regulations", substitute "regulation 5(1)(e) or (2) of the Remission of Charges Regulations",

⁽a) Paragraph 3(!ZA) of Schedule 2 was inserted by S.I. 2003/1084

⁽b) 1971 c.38

⁽c) S.I. 2001/3998

⁽d) Paragraph 3(1C) of Schedule 2 was substituted by S.I. 2003/1084

- (iv) in subparagraph (4), for the words "a doctor, a dentist, a supplementary prescriber or an independent nurse prescriber" substitute "a prescriber or a dentist",
- (v) in subparagraph (6), for the words "a doctor, dentist, supplementary prescriber or independent nurse prescriber" substitute "a prescriber or dentist",
- (vi) in subparagraph (7), for the words "the doctor, dentist, supplementary prescriber or independent nurse prescriber" substitute "the prescriber or dentist", and
- (vii) in subparagraph (9), for the words "doctor, supplementary prescriber or independent nurse prescriber" whenever they appear substitute "prescriber";
- (b) in paragraph 3A(a)—
- (i) in subparagraphs (4), (5) and (7), for the word "doctor" whenever it appears, substitute "prescriber";
- (ii) in subparagraph (9)—
 - (aa) in paragraph (c) for the words "repeatable prescribing doctor" substitute the words "repeatable prescriber", and
 - (bb) in the words following sub-paragraph (d) for the word "doctor" substitute the word "prescriber"; and
- (c) for paragraph 7(2), substitute—
- "(2) Where a chemist supplies a container in response to an order for drugs signed by a prescriber, or supplies an oxygen container or oxygen equipment, other than equipment specified in the Drug Tariff as not returnable to the chemist, the container and equipment shall remain the property of the chemist."

Amendment of Part III (terms of service for doctors who provide pharmaceutical services) of Schedule 2

- **21.** In Part III of Schedule 2—
 - (a) for paragraph 11 substitute—
 - "(11) Subject to paragraph 11A, where a doctor is authorised or required by a Primary Care Trust under regulation 20 to provide drugs or appliances to a patient—
 - (a) he shall record an order for the provision of any drugs, or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with the term of a contract which gives effect to paragraph 39(3) of Schedule 6 to the GMS Regulations or an equivalent provision applying in relation to that contract;
 - (b) he shall provide those drugs or appliances in a suitable container;
 - (c) he shall provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations only where the conditions in paragraph 42(2) of Schedule 6 to the GMS Regulations are satisfied; and
 - (d) he shall provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.";
 - (b) for paragraph 11A(2)(b) substitute—

"(2)Where a patient presents an order on a prescription form for drugs or listed appliances signed by a prescriber, or an order for a restricted availability appliance signed by and endorsed on its face with the reference "SLS" by a prescriber, to a doctor who is authorised or required by regulation 20 to provide drugs or appliances to that patient, the doctor may provide to the patient such of the drugs or appliances so ordered as he supplies in the normal course of his practice.";

⁽a) Paragraph 3A of Schedule 2 was inserted by S.I. 2003/1084

⁽b) Paragraph 11A of Schedule 2 was inserted by S.I. 1994/2002 and sub-paragraph (2) was amended by S.I. 2002/551

- (c) in paragraph 11B(a)—
 - (i) in sub-paragraph (a)(ii), for "regulation 3 of the Remission of Charges Regulations", substitute "regulation 5 of the Remission of Charges Regulations"; and
- (ii) in the words following sub-paragraph (a)(ii), for "regulation 4(2)(e), (f) or (q) of the Remission of Charges Regulations", substitute "regulation 5(1)(e) or (2) of the Remission of Charges Regulations";
- (d) for paragraphs 13 and 14 substitute—
- "13.—(1) The terms of a GMS contract giving effect to regulation 24 of, and Schedule 5 to the GMS Regulations (fees and charges) apply in respect of the provision of any drugs or appliances by a doctor as they apply in respect of prescriptions for drugs and appliances.
- (2) Where a doctor who is authorised or required by a Primary Care Trust under regulation 20 to provide drugs or appliances provides a drug or appliance under pharmaceutical services—
 - (a) in accordance with this Part; and
 - (b) had the drug or appliance been provided by a contractor providing dispensing services under a GMS contract, the contractor would have been entitled to a payment in respect of the drug or appliance by virtue of directions given by the Secretary of State under section 28T(b) of the Act,

the Primary Care Trust shall credit him with the payment.

- **14.**—(1) Where a doctor who is authorised or required by a Primary Care Trust under regulation 20 to provide drugs or appliances to a patient, or who otherwise provides pharmaceutical services—
 - (a) is a GMS contractor, or is engaged or employed by a GMS contractor, the complaints procedure established in accordance with the terms of a GMS contract which give effect to paragraph 92 of Schedule 6 to the GMS Regulations, or
 - (b) is a PMS contractor, or is engaged or employed by a PMS contractor, the complaints procedure established in accordance with the terms of a PMS agreement which give effect to paragraph 86 of Schedule 5 to the PMS Regulations,

shall apply in relation to any matter reasonably connected with his provision of pharmaceutical services as it applies as respects to services provided under that contract or agreement.

- (2) Accordingly, the term of the GMS contract which gives effect to paragraph 97 of Schedule 6 to the GMS Regulations or the equivalent provision in the PMS Regulations also applies in relation to complaints about such matters."; and
 - (e) paragraph 15 is omitted.

Amendments to Schedule 3A

22. For the entries in Schedule 3A (Primary Care Trusts specified for the purposes of repeat dispensing)(c) substitute—

"Amber Valley Primary Care Trust

Bath and North East Somerset Primary Care Trust

⁽a) Paragraph 11B of Schedule 2 was inserted by S.I. 1999/696

⁽b) Section 28T was inserted by section 175(1) of the 2003 Act

⁽c) Schedule 3A was inserted by S.I. 2003/1084

Bebington and West Wirral Primary Care Trust

Bedfordshire Heartlands Primary Care Trust

Birkenhead and Wallasey Primary Care Trust

Blackburn with Darwen Primary Care Trust

Blackwater Valley and Hart Primary Care Trust

Bradford South and West Primary Care Trust

Bristol North Primary Care Trust

Bristol South and West Primary Care Trust

Bromley Primary Care Trust

Burnley Pendle and Rossendale Primary Care Trust

Burntwood, Lichfield and Tamworth Primary Care Trust

Camden Primary Care Trust

Castle Point and Rochford Primary Care Trust

Central Cornwall Primary Care Trust

Charnwood and North West Leicestershire Primary Care Trust

Chelmsford Primary Care Trust

Cheltenham and Tewkesbury Primary Care Trust

Cheshire West Primary Care Trust

Cotswold and Vale Primary Care Trust

Coventry Primary Care Trust

Durham and Chester-le-Street Primary Care Trust

Durham Dales Primary Care Trust

East Devon Primary Care Trust

East Elmbridge and Mid Surrey Primary Care Trust

East Hampshire Primary Care Trust

East Leeds Primary Care Trust

East Yorkshire Primary Care Trust

Eastern Birmingham Primary Care Trust

Erewash Primary Care Trust

Exeter Primary Care Trust

Gateshead Primary Care Trust

Great Yarmouth Primary Care Trust

Harrow Primary Care Trust

Hartlepool Primary Care Trust

Herefordshire Primary Care Trust

Hounslow Primary Care Trust

Hyndburn and Ribble Valley Primary Care Trust

Ipswich Primary Care Trust

Leicester Primary Care Trust

Medway Primary Care Trust

Mendip Primary Care Trust

Mid Devon Primary Care Trust

Newbury and Community Primary Care Trust

Newcastle Primary Care Trust

New Forest Primary Care Trust

Newham Primary Care Trust

North Birmingham Primary Care Trust

North Hertfordshire and Stevenage Primary Care Trust

North Liverpool Primary Care Trust

North Peterborough Primary Care Trust

North Sheffield Primary Care Trust

Northamptonshire Heartlands Primary Care Trust

Northumberland Primary Care Trust

Norwich Primary Care Trust

Portsmouth City Primary Care Trust

Preston Primary Care Trust

Redditch and Bromsgrove Primary Care Trust

Sheffield West Primary Care Trust

Somerset Coast Primary Care Trust

South East Hertfordshire Primary Care Trust

South East Oxfordshire Primary Care Trust

South East Sheffield Primary Care Trust

South Gloucestershire Primary Care Trust

South Peterborough Primary Care Trust

South Warwickshire Primary Care Trust

South West Dorset Primary Care Trust

South West Oxfordshire Primary Care Trust

South Worcestershire Primary Care Trust

Southern Norfolk Primary Care Trust

Southwark Primary Care Trust

Stockport Primary Care Trust

Suffolk Coastal Primary Care Trust

Sunderland Teaching Primary Care Trust

Sutton and Merton Primary Care Trust

Taunton Deane Primary Care Trust

Torbay Primary Care Trust

Vale of Aylesbury Primary Care Trust

Wakefield West Primary Care Trust

Walsall Teaching Primary Care Trust

West Hull Primary Care Trust

West Lincolnshire Primary Care Trust

West of Cornwall Primary Care Trust

Western Sussex Primary Care Trust

Witham, Braintree and Halstead Primary Care Trust

Wolverhampton Primary Care Trust

Wycombe Primary Care Trust

Wyre Forest Primary Care Trust"

Provisions to be revoked

23.The provisions set out in the Schedule are revoked to the extent specified.

Transitional provisions

- 24.—(1) Where, prior to 1st April 2004, actions have been taken
 - (a) by or in relation to a Local Medical Committee, such actions shall be deemed to have been taken by or in relation to the Local Medical Committee which replaces it on 1st April 2004,
 - (b) by or in relation to a Community Health Council, such actions shall be deemed to have been taken by or in relation to the Patients' Forum which replaces it.
- (2) Where an outline consent has been granted to a doctor prior to 1st April 2004 it shall be deemed to continue on and after that date.
- (3) Any arrangements made under regulation 20(3)(a) or (b) of the Principal Regulations as it had effect prior to the coming into force of these Regulations shall be treated as having been made under regulation 20(4) as inserted by these Regulations.

Rosie Winterton Minister of State, Department of Health

25th March 2004

SCHEDULE 1

Regulation 23

Provisions of the Principal Regulations to be Revoked

Provision to be revoked	Extent of Revocation		
Regulation 2(1)	The definitions of:		
	"Community Health Council"		
	"doctor's list"		
	"doctors' terms of service"		
	"medical list"		
	"Medical Regulations"		
	"personal medical services"		
	"pilot scheme"		
	"pilot scheme provider"		
Regulation 2A	the entire regulation		
Regulation 12	paragraph 2A		
Regulation 13(2)(a)	Sub paragraph (iii)		
Regulation 19	the entire regulation		
Regulation 21A	the entire regulation		
Regulation 24(2)(a)	the words ", or to a doctor who provides pharmaceutical services"		
Schedule 2 paragraph 1(2)	the definition of "repeatable prescribing doctor"		
Schedule 2 paragraph 13(3)	the entire sub-paragraph		
Schedule 2 paragraph 15	the entire sub-paragraph		

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make changes to the National Health Service (Pharmaceutical Services) Regulations 1992 which are consequential upon the National Health Service (General Medical Services Contracts) Regulations 2004 and upon the National Health Service (Personal Medical Services Agreements) Regulations 2004

Regulation 24 extends the scheme which allows chemists to dispense in accordance with repeatable prescriptions, by extending it to those Primary Care Trust areas specified in the amendment.

STATUTORY INSTRUMENTS

2004 No. 922

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical Services) (Amendment) Regulations 2004

E0503 4/2004 140503T 19585

