STATUTORY INSTRUMENTS

## 2003 No. 1084

# NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Pharmaceutical Services) (General Medical Services) and (Charges for Drugs and Appliances) Amendment Regulations 2003

Made	9th April 2003
Laid before Parliament	16th April 2003
Coming into force	7th May 2003

The Secretary of State for Health, in exercise of the powers conferred on him by sections 29, 41, 42, 43, 77, 83A and 126(4) and (5) of the National Health Service Act 1977(1) and sections 35 and 38 of the Health and Social Care Act 2001(2), and of all other powers enabling him in that behalf, hereby makes the following Regulations:

#### Citation, commencement and application

**1.**—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services) (General Medical Services) and (Charges for Drugs and Appliances) Amendment Regulations 2003 and shall come into force on 7th May 2003.

<sup>1977</sup> c. 49; section 29 was extended by the Health and Medicines Act 1988 (c. 49) ("the 1988 Act"), section 17; amended (1) by the Health Services Act 1980 (c. 53) ("the 1980 Act"), sections 1 and 7 and Schedule 1, paragraph 42(b); by the Health and Social Services and Social Security Adjudications Act 1983 (c. 41), Schedule 6, paragraph 2; by the Medical Act 1983 (c. 54), section 56(1) and Schedule 5, paragraph 16(a); by S.I. 1985/39, article 7(3); by the Health Authorities Act 1995 (c. 17) ("the 1995 Act"), Schedule 1, paragraph 18; by the National Health Service (Primary Care) Act 1997 (c. 46) ("the 1997 Act"), Schedule 2, paragraph 8; by the Health and Social Care Act 2001 (c. 15) ("the 2001 Act"), section 17; and by the National Health Service Reform and Health Care Professions Act 2002 (c. 17) ("the 2002 Act"), Schedule 2, paragraph 3. Section 41 was substituted by the 2001 Act, section 42(1), and amended by the 2002 Act, Schedule 2, paragraph 13. Section 42 was substituted by the National Health Service (Amendment) Act 1986 (c. 66), section 3(1); extended by the 1988 Act, 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 1995 Act, Schedule 1, paragraph 30; by the 2001 Act, section 43(2), (3) and (4); and by the 2002 Act, Schedule 2, paragraph 16. Section 43 was amended by the 1995 Act, Schedule 1, paragraph 31; by the 1980 Act, section 21(2); by the 1997 Act, section 29(1) and Schedule 2, paragraph 14; by the 1990 Act, Schedule 9, paragraph 18(2); by the 2001 Act, section 42(2) and 43(5); and by the 2002 Act, Schedule 2, paragraph 17. Section 83A was inserted by the Social Security Act 1988 (c. 7), section 14(1), and amended by the 1988 Act, section 25 and Schedule 2, paragraph 6; by the 1990 Act, section 66(1) and Schedule 9, paragraph 18(5); by the 1995 Act, section 2(1) and Schedule 1, paragraph 40; by article 2 of S.I. 1998/2385; by article 3(1) of S.I. 2000/90; and by the 2002 Act, Schedule 2, paragraph 32. Section 126(4) was amended by the 1990 Act, section 65(2); by the Health Act 1999 (c. 8) ("the 1999 Act"), Schedule 4, paragraph 37(6); and by the 2001 Act, Schedule 5, paragraph 5(13)(b). 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 ("the 1977 Act") as amended by the 1990 Act, section 26(2)(g) and (i), for the definitions of "prescribed" and "regulations". (2)2001 c. 15.

(2) These Regulations apply to England only(3).

(3) The National Health Service (Pharmaceutical Services) Regulations 1992(4) are amended in accordance with the provisions of Part I of these Regulations.

(4) The National Health Service (General Medical Services) Regulations 1992(5) are amended in accordance with the provisions of Part II of these Regulations.

(5) The National Health Service (Charges for Drugs and Appliances) Regulations 2000(6) are amended in accordance with the provisions of Part III of these Regulations.

## PART I

## AMENDMENT OF THE NATIONAL HEALTH SERVICE (PHARMACEUTICAL SERVICES) REGULATIONS 1992

#### Amendment of regulation 2

2. In regulation 2 (interpretation), in paragraph (1)—

(a) for the definition of "Charges Regulations" substitute—

""Charges Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2000;";

- (b) in the definition of "prescription form", at the end insert "and does not include a repeatable prescription;"; and
- (c) after the definition of "Remission of Charges Regulations", insert the following definitions-

""repeat dispensing chemist" shall be construed in accordance with regulation 16B(1);

"repeat dispensing services" means pharmaceutical services which involve the provision of drugs or appliances by a chemist in accordance with a repeatable prescription;

"repeatable prescription" means a prescription contained in a form provided by a Primary Care Trust and issued by a doctor to enable a person to obtain pharmaceutical services or local pharmaceutical services, which is in the format specified in Part 1 of Schedule 6B(7) to the Medical Regulations, and which—

- (a) is generated by a computer but signed by a doctor; 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;".

<sup>(3)</sup> As regards Wales, the functions of the Secretary of State under sections 29, 41, 42, 43, 77, 83A 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.

 <sup>(4)</sup> S.I. 1992/662. Relevant amending instruments are 1993/2451, 1994/2402, 1995/644, 1996/698, 1998/681, 1999/696, 1999/2563, 2000/593, 2001/1396, 2001/2888, 2002/551, 2002/888, 2002/2469, 2002/2861 and 2003/699.

 <sup>(5)</sup> S.I. 1992/635. Relevant amending instruments are 1993/540, 1995/80, 1996/702, 1997/730, 1998/682, 1998/1664, 2000/3040, 2001/706, 2001/2890, 2001/3742, 2002/551, 2002/2469, 2002/2861 and 2003/699.

<sup>(6)</sup> S.I. 2000/620, as amended by S.I. 2000/2393, 2000/3189, 2001/746, 2001/2887, 2002/548, 2002/1386, 2002/2352 and 2003/699.

<sup>(7)</sup> Schedule 6B of the National Health Service (General Medical Services) Regulations 1992 is inserted by regulation 15 of these Regulations.

#### Amendment of regulation 4

- **3.** In regulation 4 (pharmaceutical lists)—
  - (a) in paragraph (1), for "supplemental services under regulation 16" substitute "additional professional services under regulation 16A or repeat dispensing services under regulation 16B"; and
  - (b) in paragraph (2)(b)(iii), after "pharmaceutical services" insert "(other than repeat dispensing services)".

#### Amendment of regulation 12

**4.** In regulation 12 (determination of applications in respect of controlled localities), in paragraph 4A(**8**), for sub-paragraph (c) substitute—

- "(c) any representations received by the Primary Care Trust from—
  - (i) any person specified in paragraph (1)(a), (b) or (e) or paragraph (2)(a) or (b),
  - (ii) a chemist or LPS chemist who was notified of the application pursuant to paragraph (1)(c) or paragraph (2)(c), or
  - (iii) any Health Authority or Primary Care Trust which was notified of the application pursuant to paragraph (1)(d), in so far as those representations relate to a chemist or LPS chemist.".

#### Amendment of regulation 16A

**5.** In regulation 16A(9) (additional professional services), in paragraph (2)(c)(i), for "regulation 6(1)(c) of the National Health Service (Charges for Drugs and Appliances) Regulations 1989" substitute "regulation 7(1)(c) of the Charges Regulations".

#### **Insertion of regulation 16B**

6. After regulation 16A insert the following regulation—

#### "Repeat dispensing services

**16B.**—(1) A chemist may provide repeat dispensing services if—

- (a) he satisfies the conditions in paragraph (2); and
- (b) he has undertaken, in accordance with paragraphs (3) and (4), to provide repeat dispensing services,

and a chemist who satisfies the requirements of sub-paragraphs (a) and (b) is referred to in these Regulations as a repeat dispensing chemist.

(2) The conditions referred to in paragraph (1)(a) are that the chemist—

- (a) is not a supplier of appliances only;
- (b) is included in the pharmaceutical list of a Primary Care Trust specified in Schedule 3A; and
- (c) is not participating in a pilot scheme on the use of electronic prescribing as described in regulation 2A(10).

<sup>(8)</sup> Regulation 12(4A) was inserted by S.I. 2002/2861.

<sup>(9)</sup> Regulation 16A was inserted by S.I. 1993/2451.

<sup>(10)</sup> Regulation 2A was inserted by S.I. 2001/2888.

(3) A chemist who wishes to provide repeat dispensing services must notify the Primary Care Trust in whose pharmaceutical list he is included, in writing, that he undertakes to provide those services, and that he intends to begin to provide them on a specified date.

(4) The date specified by a chemist pursuant to paragraph (3) must be—

- (a) the first day of any specified month; and
- (b) at least one week after the date on which the Primary Care Trust receives the notification specified in paragraph (3).

(5) A chemist may not provide repeat dispensing services unless he is a repeat dispensing chemist.".

#### Amendment of regulation 18

7. In regulation 18 (standards of, and payments for, drugs and appliances), in paragraph (1)(g), after "supply of drugs and appliances" insert ", repeat dispensing services".

#### Amendment of regulation 18B

8. In regulation 18B(11) (reward scheme), in paragraph (1)—

- (a) after "paragraph 3(1)", in the first place it appears, insert "or paragraph 3(1ZA)";
- (b) in sub-paragraph (i), for "immediately informed the Health Authority or Primary Care Trust of this action" substitute "informed the Primary Care Trust of this action as soon as practicable";
- (c) for sub-paragraph (ii) substitute—
  - "(ii) he provided the drugs and medicines or listed appliances pursuant to paragraph 3(1) or paragraph 3(1ZA) but had reason to believe at that time or subsequently came to have reason to believe that the order was not a genuine order for the person named on the prescription form and informed the Primary Care Trust of this belief as soon as practicable,"; and
- (d) at the end, add "and the Primary Care Trust has established that the order referred to in this paragraph was not a genuine order for the person named on the prescription form.".

#### Amendment of Schedule 2

**9.**—(1) Schedule 2 is amended as follows.

- (2) In paragraph 1 (interpretation)—
  - (a) the provisions of paragraph 1 are re-numbered as sub-paragraph (1); and
  - (b) after sub-paragraph (1) add—
    - "(2) In this Schedule—

"associated batch issue" means, in relation to a repeatable prescription, one of the batch issues relating to that prescription and containing the same date as that prescription;

"batch issue" means a form provided by a Primary Care Trust and issued by a doctor at the same time as a repeatable prescription to enable a chemist to receive payment for the provision of repeat dispensing services (or to enable an LPS chemist to receive payment for the provision of services corresponding to repeat dispensing services),

<sup>(11)</sup> Regulation 18B was inserted by S.I. 1999/696.

which is in the format specified in Part 2 of Schedule 6B to the Medical Regulations, and which—

- (a) is generated by a computer and not signed by a doctor;
- (b) relates to a particular repeatable prescription and contains the same date as that prescription;
- (c) forms part of a sequence of batch issues, the number of batch issues being 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); and

"repeatable prescribing doctor" means-

- (a) a repeatable prescribing doctor as construed in accordance with regulation 33A(1)(12) of the Medical Regulations;
- (b) a doctor who, in accordance with a pilot scheme, is named in a notification referred to in direction 12A of the Health Authorities and Primary Care Trusts Implementation of Pilot Schemes (Personal Medical Services) Directions 2002(13); or
- (c) a doctor who acts on behalf of a doctor specified in paragraph (a) or (b).

(3) In this Schedule, drugs or appliances shall be taken to be requested or provided in accordance with a repeatable prescription even if the person who wishes to obtain pharmaceutical services does not present that prescription, as long as—

- (a) the chemist has that prescription in his possession; and
- (b) that person presents, or the chemist has in his possession, an associated batch issue.".
- (3) In paragraph 3 (provision of pharmaceutical services)—
  - (a) in sub-paragraph (1)(bb), after "doctor" insert "or a supplementary prescriber";
  - (b) after sub-paragraph (1) insert—

"(1ZA) Subject to sub-paragraph (1B) and paragraph 3A(4), (7), (8) and (9), where any person—

- (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(14), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(15), signed by a repeatable prescribing doctor,
  - (ii) an order for a drug specified in Schedule 11 to the Medical 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 prescribing doctor,

<sup>(12)</sup> Regulation 33A of the National Health Service (General Medical Services) Regulations 1992 is inserted by regulation 13 of these Regulations.

<sup>(13)</sup> These Directions came into force on 9th April 2002. Direction 12A was inserted by the Strategic Health Authorities and Primary Care Trusts Implementation of Pilot Schemes (Personal Medical Services) (Amendment) (No. 2) Directions 2003. Copies of the Directions and the amending Directions are available on the Department of Health's website at www.doh.gov.uk/ pricare.pca.htm.

<sup>(14) 1971</sup> c. 38.

<sup>(15)</sup> S.I. 2001/3998.

- (iii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescribing doctor, or
- (iv) an order for a restricted availability appliance, signed by, and endorsed on its face with the reference "SLS" by, a repeatable prescribing doctor,

and also presents an associated batch issue; or

(b) requests the provision of drugs or appliances in accordance with a repeatable prescription of a kind specified in paragraph (a),

a repeat dispensing 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, in accordance with the directions contained in that repeatable prescription.";

- (c) in sub-paragraph (1A), after "prescription form" insert "or repeatable prescription, or requesting the provision of drugs or appliances in accordance with a repeatable prescription,";
- (d) in sub-paragraph (1B)—
  - (i) after "prescription form" insert "or repeatable prescription", and
  - (ii) after "paragraph 3(1)" insert "or paragraph 3(1ZA)";
- (e) for sub-paragraph (1C) substitute—

"(1C) Before providing any drugs or appliances in accordance with a prescription form or a repeatable prescription—

- (a) the chemist shall ask any person who makes a declaration that the person named on the prescription form or the repeatable prescription does not have to pay the charges specified in regulation 3(1) or (1A)(16) of the Charges Regulations by virtue of either—
  - (i) entitlement to exemption under regulation 7(1) of the Charges Regulations, or
  - (ii) entitlement to remission of such charges under regulation 3 of the Remission of Charges Regulations,

to produce satisfactory evidence of such entitlement, unless the declaration is in respect of entitlement to exemption by virtue of sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 4(2)(e), (f) or (q) of the Remission of Charges Regulations, and at the time of the declaration the chemist already has such evidence available to him; and

- (b) if no satisfactory evidence is produced to the chemist (and, where it is relevant, none is already available to him as mentioned in paragraph (a)) the chemist shall endorse the form on which the declaration is made to that effect.";
- (f) in sub-paragraph (3), for "prescription form, signed as specified in sub-paragraph (1)" substitute "prescription form or a repeatable prescription, signed as specified in subparagraph (1) or (1ZA)";
- (g) in sub-paragraph (4)—
  - (i) for "Misuse of Drugs Regulations 1985" substitute "Misuse of Drugs Regulations 2001", and
  - (ii) after "prescription form" insert "or repeatable prescription";
- (h) in sub-paragraph (6)—

<sup>(16)</sup> Paragraph (1A) of regulation 3 is inserted by regulation 19 of these Regulations.

- (i) for "Misuse of Drugs Regulations 1985" substitute "Misuse of Drugs Regulations 2001", and
- (ii) after "prescription form" insert "or repeatable prescription";
- (i) in sub-paragraph (9)—
  - (i) after "prescription form", in both places, insert "or repeatable prescription", and
  - (ii) in paragraph (b), for "Misuse of Drugs Regulations 1985" substitute "Misuse of Drugs Regulations 2001";
- (j) in sub-paragraph (10), after "prescription form" insert "or repeatable prescription";
- (k) in sub-paragraph (11), after "prescription form" insert "or repeatable prescription";
- (l) in sub-paragraph (14), after "prescription form" insert "or repeatable prescription"; and
- (m) after sub-paragraph (14) add—

"(15) If a person presents a repeatable prescription to a chemist who is not a repeat dispensing chemist, that chemist shall provide that person with the names and addresses of at least two pharmacies where he may obtain repeat dispensing services or (in the case of an LPS chemist) services corresponding to repeat dispensing services.

(16) If a person wishes to obtain repeat dispensing services from a chemist (chemist A), but his repeatable prescription is held by a different chemist or LPS chemist (chemist B), chemist A shall inform the person that he must return to chemist B to obtain repeat dispensing services (or, where chemist B is an LPS chemist, services corresponding to repeat dispensing services).

(17) A chemist shall secure that any pharmacist employed by him in connection with the provision of pharmaceutical services complies with the requirements set out in this paragraph.".

(4) After paragraph 3 (provision of pharmaceutical services), insert-

#### "Provision of repeat dispensing services

**3A.**—(1) A repeat dispensing chemist who is a pharmacist may personally dispense drugs or appliances in accordance with a repeatable prescription only if he has received training appropriate to the provision of repeat dispensing services.

(2) When he provides drugs or appliances in accordance with a repeatable prescription, a repeat dispensing chemist shall endorse the repeatable prescription to show—

- (a) the quantity of drug provided or the number of appliances provided; and
- (b) the date on which the drug or appliance is provided,

and, on the first occasion on which he provides drugs or appliances in accordance with a particular repeatable prescription, shall stamp that prescription with the chemist's stamp.

(3) A repeat dispensing chemist shall store securely at the premises from which he provides pharmaceutical services—

- (a) repeatable prescriptions;
- (b) batch issues relating to drugs or appliances which have been provided; and
- (c) if requested to do so, batch issues relating to drugs or appliances which have not yet been provided,

until such time as he is required, in accordance with the Drug Tariff, to send the repeatable prescription or batch issue to the Prescription Pricing Authority(17).

(4) A repeat dispensing chemist shall not provide any drugs or appliances in accordance with a repeatable prescription—

- (a) after the period of one year has elapsed since the date of the repeatable prescription; or
- (b) where the doctor who issued the repeatable prescription has marked on it an earlier expiry date, after that date.

(5) A repeat dispensing chemist shall destroy any batch issues relating to drugs or appliances which—

- (a) are not required; or
- (b) should not be provided because—
  - (i) the chemist has been notified to that effect by the doctor who issued those batch issues, or
  - (ii) the repeatable prescription to which those batch issues relate has expired.

(6) Before providing any drugs or appliances in accordance with a repeatable prescription, a repeat dispensing chemist shall refer to that prescription and shall make inquiries in order to satisfy himself—

- (a) that the person named on the repeatable prescription—
  - (i) is taking or using, and is likely to continue to take or use, the drugs or appliances appropriately, and
  - (ii) is not suffering any side effects which lead the repeat dispensing chemist to conclude that the repeatable prescription ought to be reviewed; and

(b) that there are no other reasons why the drugs or appliances should not be provided.

(7) If a repeat dispensing chemist is not satisfied as mentioned in sub-paragraph (6), or at any other time has reason to be concerned about the safety or appropriateness of a person receiving drugs or appliances ordered on a repeatable prescription—

- (a) he shall, if he considers it appropriate, do one or both of the following-
  - (i) inform the person that he should make an appointment to see his doctor, and
  - (ii) contact the doctor who issued the prescription as soon as is practicable; and
- (b) he may refuse to provide the drugs or appliances so ordered until he is so satisfied, and if he has refused to provide the drugs or appliances, he shall inform the doctor who issued that prescription of that fact as soon as is practicable.

(8) A repeat dispensing chemist shall provide drugs or appliances in accordance with a repeatable prescription only at the intervals specified in that prescription; and if the repeatable prescription does not specify intervals, the repeat dispensing chemist shall use his professional expertise to determine the intervals at which the drugs or appliances should be provided.

- (9) Where a person—
  - (a) requests the provision of drugs or appliances in accordance with a repeatable prescription which he believes to be held by a repeat dispensing chemist, but that chemist has no record of that prescription;

<sup>(17)</sup> The Prescription Pricing Authority is a Special Health Authority constituted under section 11 of the 1977 Act; seeS.I. 1990/1718.

- (b) requests the provision of drugs or appliances in accordance with a repeatable prescription, but does not present (and the chemist does not have in his possession) any associated batch issues;
- (c) presents a repeatable prescription which is not signed by a repeatable prescribing doctor; or
- (d) requests the provision of drugs or appliances in accordance with a batch issue which contains an irregularity (for example the drug or dosage specified in the batch issue differs from that specified in the repeatable prescription to which that batch issue relates),

the repeat dispensing chemist shall refuse to provide the drugs or appliances in question, and shall advise the person to contact the doctor who issued the prescription or batch issue as soon as possible.

(10) A repeat dispensing chemist shall secure that any pharmacist employed by him in connection with the provision of repeat dispensing services complies with the requirements of this paragraph.".

- (5) In paragraph 5 (provision of drugs and fitting of appliances), in sub-paragraph (2)—
  - (a) after "paragraph 3(1)" insert "or paragraph 3(1ZA)"; and
  - (b) after "prescription form" insert "or repeatable prescription".
- (6) In paragraph 8 (remuneration of chemists), after sub-paragraph (2A) insert—

"(2B) The Primary Care Trust shall make such payments, if any, as are provided for by the Drug Tariff (or by any determination made by virtue of regulation 18(1A)) to chemists who provide repeat dispensing services."

- (7) In paragraph 11B, in sub-paragraph (a)—
  - (a) for "regulation 3(1) of the Charges Regulations" substitute "regulation 4(1) of the Charges Regulations";
  - (b) in head (i), for "regulation 6(1) of the Charges Regulations" substitute "regulation 7(1) of the Charges Regulations";
  - (c) in head (ii), for "regulation 3 of the Remission of Charges Regulations, or under regulation 5 of the Remission of Charges Amendment Regulations", substitute "regulation 3 of the Remission of Charges Regulations"; and
  - (d) for "sub-paragraph (a), (b), (c), (d), (e) or (f) of regulation 6(1) of the Charges Regulations", substitute "sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 4(2) (e), (f) or (q) of the Remission of Charges Regulations".

#### **Insertion of Schedule 3A**

10. After Schedule 3, the following Schedule shall be inserted as Schedule 3A—

#### **"SCHEDULE 3A**

Regulation 16B

#### PRIMARY CARE TRUSTS SPECIFIED FOR THE PURPOSES OF REPEAT DISPENSING

Amber Valley Primary Care Trust

Bebington and West Wirral Primary Care Trust

Birkenhead and Wallasey Primary Care Trust

Blackburn with Darwen 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 Central Cornwall Primary Care Trust Charnwood and North West Leicestershire Primary Care Trust Cheltenham and Tewkesbury Primary Care Trust **Coventry Primary Care Trust** Durham and Chester-le-Street Primary Care Trust Durham Dales Primary Care Trust East Elmbridge and Mid Surrey Primary Care Trust East Leeds Primary Care Trust Eastern Birmingham Primary Care Trust Erewash Primary Care Trust Gateshead Primary Care Trust Great Yarmouth Primary Care Trust Newbury and Community Primary Care Trust Newham Primary Care Trust North Birmingham Primary Care Trust North Hertfordshire and Stevenage Primary Care Trust Northumberland Primary Care Trust Portsmouth City Primary Care Trust Preston Primary Care Trust Sheffield West Primary Care Trust South East Sheffield Primary Care Trust Suffolk Coastal Primary Care Trust Taunton Deane Primary Care Trust Western Sussex Primary Care Trust.".

## PART II

# AMENDMENT OF THE NATIONAL HEALTH SERVICE (GENERAL MEDICAL SERVICES) REGULATIONS 1992

#### Amendment of regulation 2

**11.** In regulation 2 (interpretation), in paragraph (1)—

(a) after the definition of "assistant" insert the following definition—

""batch issue" means a form provided by a Primary Care Trust and issued by a doctor 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 6B, and which—

- (a) is generated by a computer and not signed by a doctor;
- (b) relates to a particular repeatable prescription and contains the same date as that prescription;
- (c) forms part of a sequence of batch issues, the number of batch issues being 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)"; and
- (b) after the definition of "relevant service" insert the following definitions-

""repeat dispensing services" means pharmaceutical services or local pharmaceutical services which involve the provision of drugs or appliances by a chemist in accordance with a repeatable prescription;

"repeatable prescribing doctor" shall be construed in accordance with regulation 33A(1);

"repeatable prescribing list" shall be construed in accordance with regulation 33A(9);

"repeatable prescribing services" means general medical services which involve the prescribing of drugs or appliances on a repeatable prescription;

"repeatable prescription" means a prescription contained in a form provided by a Primary Care Trust and issued by a doctor to enable a person to obtain pharmaceutical services or local pharmaceutical services, which is in the format specified in Part 1 of Schedule 6B, and which—

- (a) is generated by a computer but signed by a doctor; 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;".

#### Amendment of regulation 4

12. In regulation 4 (medical list), in paragraph (4), after sub-paragraph (c) insert—

"(ca) if he is included in the repeatable prescribing list;".

#### **Insertion of regulation 33A**

13. After regulation 33 (obtaining minor surgery services), insert the following regulation—

#### "Repeatable prescribing services

**33A.**—(1) Subject to paragraphs (7) and (8), a doctor may provide repeatable prescribing services to any person on his list of patients if that doctor—

- (a) satisfies the conditions in paragraph (2); and
- (b) has notified the Primary Care Trust of his intention to provide repeatable prescribing services in accordance with paragraphs (3) and (4),

and a doctor who satisfies the requirements of sub-paragraphs (a) and (b) is referred to in these Regulations as a repeatable prescribing doctor.

(2) The conditions referred to in paragraph (1)(a) are—

- (a) the doctor is included in the medical list of a Primary Care Trust specified in Schedule 6A;
- (b) the doctor has access to computer systems and software which enable him to issue repeatable prescriptions and batch issues;
- (c) the doctor is not participating in a pilot scheme on the use of electronic prescribing as described in paragraph 1A of Schedule 2(18); and
- (d) the practice premises is located in a Primary Care Trust's area in which there is also located the premises of at least one chemist who has undertaken to provide, or has entered into an arrangement to provide, repeat dispensing services.

(3) The notification referred to in paragraph (1)(b) is a notification, in writing, by a doctor to the Primary Care Trust in whose medical list he is included, that the doctor—

- (a) wishes to provide repeatable prescribing services;
- (b) intends to begin to provide those services from a specified date; and
- (c) satisfies the conditions in paragraph (2).

(4) The date specified by a doctor pursuant to paragraph (3)(b) must be at least one week after the date on which the Primary Care Trust receives the notification specified in paragraph (3).

(5) A doctor may not provide repeatable prescribing services unless—

- (a) he is a repeatable prescribing doctor; or
- (b) he is acting on behalf of a repeatable prescribing doctor pursuant to paragraph 19 of Schedule 2.

(6) Nothing in this regulation requires a doctor to provide repeatable prescribing services to any person.

(7) A doctor may provide repeatable prescribing services to a person on a particular occasion only if—

- (a) that person has agreed to receive such services on that occasion; and
- (b) the doctor considers that it is clinically appropriate to provide such services to that person on that occasion.

(8) A doctor may not provide repeatable prescribing services to any patient of his to whom he is authorised or required by the Primary Care Trust under regulation 20 of the Pharmaceutical Regulations to provide pharmaceutical services.

(9) A Primary Care Trust must maintain a list, in these Regulations referred to as a repeatable prescribing list, of the names of those doctors included in its medical list who are repeatable prescribing doctors.".

#### **Amendment of Schedule 2**

14.—(1) Schedule 2 (terms of service for doctors) is amended as follows.

(2) In paragraph 1 (interpretation), in the definition of "prescription form", at the end insert "and does not include a repeatable prescription;".

(3) In paragraph 19—

- (a) in sub-paragraph (2), for "sub-paragraphs (3), (5) and (6)" substitute "sub-paragraphs (3), (5), (6) and (6A)"; and
- (b) after sub-paragraph (6) insert—

<sup>(18)</sup> Paragraph 1A of Schedule 2 was inserted by S.I. 2001/2890.

"(6A) In the case of repeatable prescribing services, a repeatable prescribing doctor shall not arrange for the provision of such services by any person who is not a doctor.".

- (4) In paragraph 40, after "prescription" insert "or repeatable prescription".
- (5) In paragraph 42, after "prescription" insert "or repeatable prescription".
- (6) In paragraph 43 (prescribing)—
  - (a) in sub-paragraph (1)—
    - (i) after "prescription form", in the first place it appears, insert "or a repeatable prescription", and
    - (ii) for "such a form" substitute "such a prescription form or repeatable prescription";
  - (b) after sub-paragraph (1) insert—

"(1A) A doctor may order drugs or appliances on a repeatable prescription only where the drugs or appliances so ordered are to be provided more than once.";

- (c) in sub-paragraph (2)—
  - (i) after "prescription form", in both places, insert "or repeatable prescription",
  - (ii) for "the form", in both places, substitute "the prescription form or repeatable prescription", and
  - (iii) in paragraph (a), for "prescription", in both places, substitute "prescription form or repeatable prescription";
- (d) in sub-paragraph (3), for "Misuse of Drugs Regulations 1985 (controlled drugs to which regulations 14, 15, 16, 18, 19, 20, 21, 23, 25 and 26 of those Regulations apply)", substitute "Misuse of Drugs Regulations 2001 (controlled drugs to which regulations 14, 15, 16, 18, 19, 20, 21, 23, 26 and 27 of those Regulations apply)";
- (e) in sub-paragraph (5)—
  - (i) after "prescription form", in both places, insert "or repeatable prescription", and
  - (ii) for "Misuse of Drugs Regulations 1985" substitute "Misuse of Drugs Regulations 2001"; and
- (f) in sub-paragraph (6)—
  - (i) after "prescription form", in both places, insert "or repeatable prescription", and
  - (ii) for "Misuse of Drugs Regulations 1985" substitute "Misuse of Drugs Regulations 2001".
- (7) After paragraph 43 insert—

#### "Repeatable prescribing services

**43A.**—(1) A doctor who issues a repeatable prescription must at the same time issue the appropriate number of batch issues.

(2) A doctor who has provided repeatable prescribing services to a person must, as soon as is practicable, notify that person, and make every effort to contact the chemist providing repeat dispensing services to that person, if—

- (a) he makes any change to the type, quantity, strength or dosage of drugs or appliances ordered on that person's repeatable prescription; or
- (b) he considers that it is no longer appropriate or safe for that person to receive the drugs or appliances ordered on his repeatable prescription, or no longer appropriate or safe for him to continue to receive repeatable prescribing services.

(3) If a doctor provides repeatable prescribing services to a person in respect of whom he has previously issued a repeatable prescription which has not yet expired (for example, because that person wishes to obtain the drugs or appliances from a different chemist), the doctor must make every effort to notify the chemist which has in its possession the repeatable prescription which is no longer required.

(4) If a doctor has issued a repeatable prescription in respect of a person, and (before the expiry of that repeatable prescription) that person is removed from that doctor's list of patients, that doctor must—

- (a) notify that person; and
- (b) make every effort to notify the chemist who has been providing repeat dispensing services to that person,

that the repeatable prescription should no longer be used to obtain or provide repeat dispensing services.".

- (8) In paragraph 44—
  - (a) after "prescription form", in each of the places it appears, insert "or repeatable prescription"; and
  - (b) after sub-paragraph (3) add—

"(4) In the course of treating such a patient a doctor shall not order on a repeatable prescription 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, but may otherwise prescribe such a drug for that patient in the course of that treatment."

(9) In paragraph 46, for "paragraphs 43 and 44" substitute "paragraphs 43, 43A and 44".

(10) In paragraph 49 (inquiries about prescriptions and referrals), in sub-paragraph (1)(a), after "prescription form" insert "or repeatable prescription".

#### Insertion of Schedules 6A and 6B

**15.** After Schedule 6 (minor surgery procedures), the following Schedules shall be inserted as Schedules 6A and 6B—

#### **"SCHEDULE 6A**

Regulation 33A

#### PRIMARY CARE TRUSTS SPECIFIED FOR THE PURPOSES OF REPEATABLE PRESCRIBING

Amber Valley Primary Care Trust

Bebington and West Wirral Primary Care Trust

Birkenhead and Wallasey Primary Care Trust

Blackburn with Darwen 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

Central Cornwall Primary Care Trust

Charnwood and North West Leicestershire Primary Care Trust

Cheltenham and Tewkesbury Primary Care Trust

**Coventry Primary Care Trust** Durham and Chester-le-Street Primary Care Trust Durham Dales Primary Care Trust East Elmbridge and Mid Surrey Primary Care Trust East Leeds Primary Care Trust Eastern Birmingham Primary Care Trust Erewash Primary Care Trust Gateshead Primary Care Trust Great Yarmouth Primary Care Trust Newbury and Community Primary Care Trust Newham Primary Care Trust North Birmingham Primary Care Trust North Hertfordshire and Stevenage Primary Care Trust Northumberland Primary Care Trust Portsmouth City Primary Care Trust Preston Primary Care Trust Sheffield West Primary Care Trust South East Sheffield Primary Care Trust Suffolk Coastal Primary Care Trust Taunton Deane Primary Care Trust Western Sussex Primary Care Trust.

#### **SCHEDULE 6B**

Regulation 2(1)

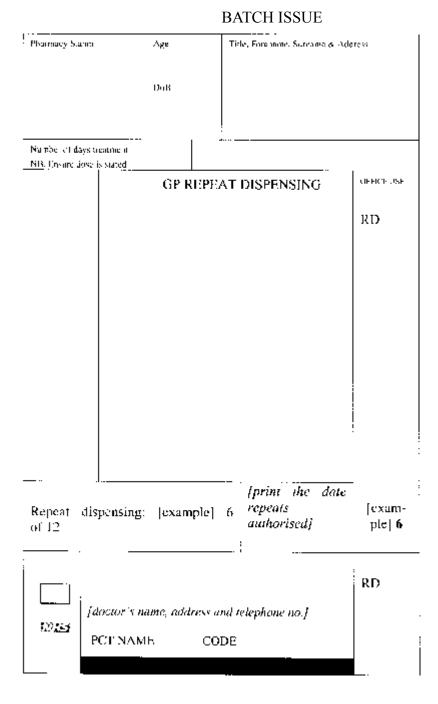
### **REPEAT DISPENSING FORMS**

# PART 1

## **REPEATABLE PRESCRIPTION**

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## PART 2



#### **Amendment of Schedule 12**

16. In Schedule 12 (information to be included in practice leaflets), after paragraph 10 insert—

"10A. If the doctor is a repeatable prescribing doctor, the arrangements for providing repeatable prescribing services."

#### Amendment of Schedule 13

17. In Schedule 13 (information to be provided in annual reports), after paragraph 2 insert—

**"2A.** If the doctor is a repeatable prescribing doctor, the arrangements for providing repeatable prescribing services.".

## PART III

## AMENDMENT OF THE NATIONAL HEALTH SERVICE (CHARGES FOR DRUGS AND APPLIANCES) REGULATIONS 2000

#### Amendment of regulation 2

18. In regulation 2 (interpretation)—

- (a) in paragraph (1)—
  - (i) after the definition of "appliance", insert the following definition-

""batch issue" means a form provided by a Primary Care Trust and issued by a doctor 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 6B(19) to the National Health Service (General Medical Services) Regulations 1992, and which—

- (a) is generated by a computer and not signed by a doctor;
- (b) relates to a particular repeatable prescription and contains the same date as that prescription;
- (c) forms part of a sequence of batch issues, the number of batch issues being 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);", and
- (ii) for the definition of "prescription form"(20) substitute the following definitions—

""prescription form" means, subject to regulation 2A, a form provided by an NHS trust or a Primary Care Trust and issued by a doctor, dentist, supplementary prescriber or independent nurse prescriber to enable a person to obtain pharmaceutical services or local pharmaceutical services and—

- (a) includes a prescription form provided and issued under equivalent arrangements having effect in Scotland, Wales or Northern Ireland; and
- (b) does not include a repeatable prescription;

"repeat dispensing services" means pharmaceutical services or local pharmaceutical services which involve the provision of drugs or appliances by a chemist in accordance with a repeatable prescription;

"repeatable prescription" means a prescription contained in a form provided by a Primary Care Trust and issued by a doctor to enable a person to obtain pharmaceutical services or local pharmaceutical services, which is in the format specified in Part 1 of Schedule 6B to the National Health Service (General Medical Service) Regulations 1992, and which—

<sup>(19)</sup> S.I. 1992/635; Schedule 6B is inserted by regulation 15 of these Regulations.

<sup>(20)</sup> As amended by S.I. 2001/2887 and S.I. 2002/2352.

- (a) is generated by a computer but signed by a doctor, 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;"; and
- (b) in paragraph (3), after "one prescription form" insert ", or on one repeatable prescription (but only where the supply is against one batch issue relating to that repeatable prescription)".

#### Amendment of regulation 3

**19.**—(1) Regulation 3 (supply of drugs and appliances by chemists) is amended as follows.

(2) In paragraph (1), for "A chemist" substitute "Except as provided in paragraph (1A), a chemist".

(3) After paragraph (1) insert—

"(1A) A chemist who provides repeat dispensing services to a patient shall, subject to paragraph (3), make and recover from that patient in respect of each batch issue—

- (a) in respect of an item of elastic hosiery a charge of £6.30, that is to say a charge of £12.60 per pair;
- (b) in respect of the supply of each other appliance and of each quantity of a drug, a charge of £6.30.

(1B) Where a charge is paid under paragraph (1A), the person making the payment shall on doing so sign a declaration in writing on the batch issue that the relevant charge has been paid.".

(4) For paragraph (3) substitute—

"(3) No charges shall be made and recovered under paragraph (1) or paragraph (1A) where—

- (a) there is exemption under regulation 7 and a declaration of entitlement to exemption is duly completed by or on behalf of the patient—
  - (i) in cases falling within paragraph (1A), on the batch issue at the time that the drug or appliance is supplied,
  - (ii) in cases involving a prescription form falling within regulation 2A, in such other written or alternative form as the Secretary of State is satisfied is suitable for the purposes of a pilot scheme on the use of electronic prescribing, or
  - (iii) in all other cases, on the prescription form;
- (b) there is entitlement to remission of the charge under regulation 3 of the Travelling Expenses and Remission of Charges Regulations and a declaration of entitlement to remission is duly completed by or on behalf of the patient either—
  - (i) in cases falling within paragraph (1A), on the batch issue at the time that the drug or appliance is supplied,
  - (ii) in cases involving a prescription form falling within regulation 2A, in such other written or alternative form as the Secretary of State is satisfied is suitable for the purposes of a pilot scheme on the use of electronic prescribing, or
  - (iii) in all other cases, on the prescription form; or

- (c) the patient is resident in a school or institution the name of which is inserted on the prescription form by a doctor under paragraph 45 of Schedule 2 to the National Health Service (General Medical Services) Regulations 1992(21) or under an equivalent provision of a pilot scheme."
- (5) In paragraph (5)—
  - (a) after "prescription form" insert "or repeatable prescription"; and
  - (b) after "paragraph (1)" insert "or paragraph (1A)".
- (6) In paragraph (6), after "paragraph (1)" insert "or paragraph (1A)".

Signed by authority of the Secretary of State for Health

David Lammy Parliamentary Under Secretary of State, Department of Health

9th April 2003

(21) S.I. 1992/635. Paragraph 45 was amended by regulation 31(1) and (4)(c) of S.I. 2002/2861.

#### **EXPLANATORY NOTE**

(This note is not part of the Regulations)

These Regulations make amendments to certain other National Health Service Regulations to establish schemes for repeat dispensing, which involve doctors issuing, and chemists dispensing in accordance with, repeatable prescriptions.

The Regulations apply to certain areas of England only. Those Primary Care Trust areas which are covered are specified in amendments to the National Health Service (Pharmaceutical Services) Regulations 1992 ("the Pharmaceutical Regulations") and the National Health Service (General Medical Services) Regulations 1992 ("the Medical Regulations") (see regulations 10 and 15 of these Regulations).

Part I of the Regulations amends the Pharmaceutical Regulations. The main changes are as follows:

- regulation 2 inserts definitions into regulation 2 of the Pharmaceutical Regulations;
- regulation 6 adds regulation 16B to the Pharmaceutical Regulations, specifying those chemists who are eligible to provide repeat dispensing services, and how they should notify the Primary Care Trust that they wish to do so; and
- regulation 9 amends Schedule 2 to the Pharmaceutical Regulations (chemists' terms of service), and makes provision regarding the dispensing of repeatable prescriptions. In particular, it inserts paragraph 3A into that Schedule which makes specific provision for the dispensing of such prescriptions (regulation 9(4)), for example concerning the endorsement and storage of such prescriptions by chemists and the circumstances in which chemists must or may refuse to dispense such a prescription.

Regulations 4, 5 and 8 of these Regulations make further minor amendments to the Pharmaceutical Regulations, unconnected with repeat dispensing schemes.

Part II of the Regulations amends the Medical Regulations. The main changes are as follows:

- regulation 11 inserts definitions into regulation 2 of the Medical Regulations;
- regulation 13 inserts regulation 33A into the Medical Regulations, specifying those doctors who are eligible to issue repeatable prescriptions, and how they should notify the Primary Care Trust that they wish to do so;
- regulation 14 amends Schedule 2 to the Medical Regulations (doctors' terms of service) to provide for the issuing of repeatable prescriptions, and in particular inserts paragraph 43A into that Schedule, which makes specific provision in connection with such prescriptions (regulation 14(7)); and
- regulation 15 inserts Schedule 6B into the Medical Regulations, specifying the format of the repeatable prescription and batch issue forms that must be issued in connection with repeat dispensing.

Part III of the Regulations amends the National Health Service (Charges for Drugs and Appliances) Regulations 2000 ("the Charges Regulations"). The main changes are as follows:

— regulation 18 inserts definitions into regulation 2 of the Charges Regulations, and also amends regulation 2 to ensure that where more than one container of drugs, or more than one appliance (subject to specified exceptions) is provided in reliance on one batch issue, only one charge is payable; and **Status:** This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

— regulation 19 amends regulation 3 of the Charges Regulations, to clarify that the specified charges are payable on each batch issue, requiring a person paying such a charge to sign a declaration that the charge has been paid, and specifying that the exemptions, remissions, requirement for the charge to be paid and requirement to issue a receipt, which apply to all other charges under the Charges Regulations, also apply to charges for repeat dispensing services.