STATUTORY INSTRUMENTS

# 2003 No. 1084

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

## 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(1) 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;".

## Amendment of regulation 4

**3.** In regulation 4 (pharmaceutical lists)—

<sup>(1)</sup> Schedule 6B of the National Health Service (General Medical Services) Regulations 1992 is inserted by regulation 15 of these Regulations.

- (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(2), 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(3) (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(4).

(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.

<sup>(2)</sup> Regulation 12(4A) was inserted by S.I. 2002/2861.

<sup>(3)</sup> Regulation 16A was inserted by S.I. 1993/2451.

<sup>(4)</sup> Regulation 2A was inserted by S.I. 2001/2888.

- (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(5) (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), 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;

<sup>(5)</sup> Regulation 18B was inserted by S.I. 1999/696.

- (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)(6) 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(7); 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(8), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001(9), 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,
  - (iii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescribing doctor, or

<sup>(6)</sup> Regulation 33A of the National Health Service (General Medical Services) Regulations 1992 is inserted by regulation 13 of these Regulations.

<sup>(7)</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>(</sup>**8**) 1971 c. 38.

<sup>(9)</sup> S.I. 2001/3998.

(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)(10) 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 sub-paragraph (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)—
  - (i) for "Misuse of Drugs Regulations 1985" substitute "Misuse of Drugs Regulations 2001", and

<sup>(10)</sup> Paragraph (1A) of regulation 3 is inserted by regulation 19 of these Regulations.

(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(11).

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

(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;
- (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.".