WELSH STATUTORY INSTRUMENTS

2004 No. 1018 (W.115)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (Pharmaceutical Services etc.), (Repeatable Prescriptions) (Amendment) (Wales) Regulations 2004

Made	-	-	-	-		31st March 2004
Coming	into	force		-	-	1st April 2004

The National Assembly for Wales, in exercise of the powers conferred upon it by sections 29, 41, 42, 43, 77, 83A and 126(4) of the National Health Service Act 1977(1) hereby makes the following Regulations:

Citation, commencement, effect and application

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services etc) (Repeatable Prescriptions) (Amendment) (Wales) Regulations 2004.

(2) These Regulations come into force on 1st April 2004.

^{(1) 1977} c. 49. Section 29 was extended by the Health and Medicines Act 1988 (c. 49), section 17; and amended by the Health Services Act 1980 (c. 53), sections 1 and 7 and Schedule 2, paragraph 16(a); by S.I.1985/39, article 7(3); by the Health Authorities Act 1995 (c. 17), Schedule 1, paragraph 18 and by the National Health Service (Primary Care) Act 1997 (c. 46), Schedule 2, paragraph 8.

Section 41 was substituted by the Health and Social Care Act 2001(c. 15), section 42(1).

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 SI 1987/2202, article 4; by the 1990 Act, section 12(3) and by the 1995 Act, Schedule 1, paragraph 30.

Section 43 was amended by the 1980 Act, Schedule 9, paragraph 18(2); by the 1995 Act, Schedule 1, paragraph 31; and by the 1997 Act, section 29(1) and Schedule 2, paragraph 14.

Section 83A was inserted by the Social Security Act 1988 (c. 7), section 14(1); amended by the Health and Medicines Act 1988 (c. 49), Schedule 2, paragraph 6; by the 1990 Act, Schedule 9, paragraph 18(5); by the 1995 Act, Schedule 1, paragraph 40 and by article 2 of S.I.1998/2385.

See section 128(1) as amended by the National Health Service and Community Care Act 1990 (c. 19) ("the 1990 Act"), section 26(2)(g) and (i), and by the Health Act 1999 (c. 8) ("the 1999 Act), Schedule 4, paragraph 38(2)(b), for the definitions of "prescribed" and "regulations".

Section 126(4) was amended by the 1990 Act, section 65(2) and the 1999 Act, Schedule 4, paragraph 37(6).

The functions of the Secretary of State under sections 29, 41, 42, 43, 77, 83A and 126(4) of the National Health Service Act 1977 were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999, S.I.1999/672, article 2 and Schedule 1, as amended by the 1999 Act, section 66(4), the Health and Social Care Act 2001 (c. 15), section 68(1), National Health Service Reform and Health Care Professions Act 2002 (c. 17), section 40(1) and the Health and Social Care (Community Health and Standards) Act 2003 (c. 43), section 197(1).

(3) The National Health Service (Pharmaceutical Services) Regulations 1992(2) are amended in accordance with Part 1 of these Regulations.

(4) The National Health Service (Charges for Drugs and Appliances) (Wales) 2001(3) are amended in accordance with Part 2 of these Regulations.

(5) These Regulations apply to Wales only.

PART 1

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 "appropriate non-proprietary name" substitute the following definition—

""appropriate non-proprietary name" means a non-proprietary name which is not mentioned in Schedule 1 to the National Health Service (General Medical Services Contract) (Prescription of Drugs etc.)(Wales) Regulations 2004(4), or except where the conditions in regulation 3 of those Regulations are satisfied, in Schedule 2 to those Regulations;";

(b) after the definition of "preliminary consent", insert the following definition-

"prescriber" means-

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

""repeat dispensing chemist" is to 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 Local Health Board and issued by a prescriber to enable a person to obtain pharmaceutical services which is in the format specified in Part I of Schedule 1 to the NHS (General Medical Services Contracts) (Wales) Regulations 2004(5), and which —

(a) is generated by a computer but signed by a prescriber; and

⁽²⁾ S.I.1992/662; the relevant amending instruments are S.I.1999/696, 2001/1396, 2002/3189, 2003/139, 783 and 3236.

⁽³⁾ S.I.2001/1358; the relevant amending instrument is S.I.2001/2359.

⁽⁴⁾ S.I.2004/1022 (W.119).

⁽⁵⁾ S.I.2004/478 (W.48).

- (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
- (e) for the definition of "Scheduled drug" substitute the following definition-

""Scheduled drug" means a drug or other substance specified in Schedule 1 to the National Health Service (General Medical Services Contracts)(Prescription of Drugs etc.) (Wales) Regulations 2004, or except where the conditions in regulation 3 of those Regulations are satisfied, in Schedule 2 to those 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)".

Insertion of regulation 16B

4.—(1) After regulation 16A insert the following regulation—

"Repeat dispensing services

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

- (a) he or she satisfies the condition in paragraph (2); and
- (b) he or she 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 condition referred to in paragraph (1)(a) is that the chemist is not a supplier of appliances only.

(3) A chemist who wishes to provide repeat dispensing services must notify the Local Health Board in whose pharmaceutical list he or she is included, in writing, undertaking to provide those services and specifying the date upon which he or she will begin to provide them.

(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 notification specified in paragraph (3) is given to the Local Health Board.

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

Amendment of regulation 18

5. 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 Schedule 2

- 6.—(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 provide by a Local Health Board 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 I of Schedule 1 to the National Health Service (General Medical Services Contracts)(Wales) Regulations 2004, 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) 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 paragraph (c).

(3) In this Schedule, drugs or appliances will 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 or her possession; and
- (b) that person presents, or the chemist has in his or her possession, an associated batch issue.".
- (3) In paragraph 3 (provision of pharmaceutical services)
 - (a) in sub-paragraph (1)(b), for "Schedule 11 to the Medical Regulations" substitute "Schedule 2 to the National Health Service (General Medical Services Contracts) (Prescription of Drugs etc) (Wales) Regulations 2004";
 - (b) in sub-paragraph (1)(bb), after "doctor" insert "or a supplementary prescriber";
 - (c) 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, other than a drug which is for the time being specified in Schedule 4 or 5 of the Misuse of Drugs Regulations 2001, signed by a prescriber,
 - (ii) an order for a drug specified in Schedule 2 to the National Health Service (General Medical Services Contracts)(Prescription of Drugs etc) (Wales) Regulations 2004, 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 Schedules 4 or 5 of the Misuse of Drugs Regulations

2001, signed by, and endorsed on its face with the reference "SLS", by a prescriber,

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

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 must, with reasonable promptness, provide the drugs so ordered and such of the appliances so ordered as he or she supplies in the normal course or his or her business, in accordance with the directions contained in that repeatable prescription.";

- (d) 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,";
- (e) in sub-paragraph (1B)—
 - (i) after "prescription form" insert "or repeatable prescription", and
 - (i) after "paragraph 3(1)" insert "or paragraph 3(1ZA)";
- (f) 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 must 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) of the Charges Regulations by virtue of either—
 - (i) entitlement to exemption under regulation 8(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 regulation 8(1) of the Charges Regulations or in respect of entitlement to remission by virtue of regulation 4(2) (e), (j) or (k) of the Remission of Charges Regulations, and at the time of the declaration, the chemist already has such evidence available to him or her; and

- (b) if no satisfactory evidence is produced to the chemist (and, where it is relevant, none is readily available to him or her as mentioned in paragraph (a)) the chemist must endorse the form on which the declaration is made to that effect.";
- (g) in sub-paragraph (3), for "prescription form, signed as a specified in sub-paragraph (1)" substitute "prescription form or a repeatable prescription, signed as specified in subparagraph (1) or (1ZA)";
- (h) in sub-paragraph (4), after "prescription form" insert "or repeatable prescription";
- (i) in sub-paragraph (6), after "prescription form" insert "or repeatable prescription";
- (j) in sub-paragraph (9), after "prescription form", in both places, insert "or repeatable prescription";
- (k) in sub-paragraph (10), after "prescription form" insert "or repeatable prescription";

- (l) in sub-paragraph (11), after "prescription form" insert "or repeatable prescription";
- (m) in sub-paragraph (14), after "prescription form" insert "or repeatable prescription";
- (n) 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 must provide the person with the names and addresses of at least two pharmacies where the person may obtain repeat dispensing services.

(16) If a person wishes to obtain repeat dispensing services from a chemist (chemist A), but the person's repeatable prescription is held by a different chemist (chemist B), chemist A must inform the person that he or she must return to chemist B to obtain repeat dispensing services.

(17) A chemist must secure that any pharmacist employed by him or her 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 or she has received training appropriate to the provision of repeat dispensing services.

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

- (a) the quantity of the 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 upon which he or she provides drugs or appliances in accordance with a particular repeatable prescription, must stamp that prescription with the chemist's stamp.

(3) A repeat dispensing chemist must store securely at the premises from which he or she 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 issued relating to drugs or appliances which have not yet been provided,

until such time as he or she is required, in accordance with the requirements set out in the Drug Tariff, to send the repeatable prescription or batch issue to Health Solutions Wales.

(4) A repeat dispensing chemist must 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 prescriber who issued the repeatable prescription has marked on it an earlier expiry date, after that date.

(5) A repeat dispensing chemist must 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 prescriber 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 must refer to that prescription and must make inquiries in order to satisfy himself or herself—

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

(8) A repeat dispensing chemist must provide drugs and 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 must use his or her 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 or she 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 or her possession) any associated batch issues;
- (c) presents a repeatable prescription which is not signed by a prescriber; 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 must refuse to provide the drugs or appliances in question, and must advise the person to contact the prescriber who issued the prescription or batch issue as soon as possible.

(10) A repeat dispensing chemist must secure that any pharmacist employed by him or her 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 Local Health Board 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)" substitute "regulation 4(1)";
 - (b) omit "sub-paragraph (a), (b), (c), (d) or (e) of";
 - (c) after "regulation 8(1) of the Charges Regulations" insert "or in respect of entitlement to remission by virtue of regulation 4(2)(e), (j) or (k) or the Remission of Charges Regulations".

PART 1

AMENDMENT OF THE NATIONAL HEALTH SERVICE (CHARGES FOR DRUGS AND APPLIANCES) (WALES) REGULATIONS 2001

Amendment of regulation 2

- 7. 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 Local Health Board 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 I of Schedule 1 to the National Health Service (General Medical Services Contracts)(Wales) Regulations 2004(6), 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) 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);",
- (ii) after the definition of "pre-payment certificate", insert the following definition-

"prescriber" means-

- (a) a doctor,
- (b) an independent nurse prescriber, and
- (c) a supplementary prescriber;",
- (iii) for the definition of "prescription form" substitute the following definition-

⁽⁶⁾ S.I.2004/478 (W.48).

""prescription form" means, a form provided by a Local Health Board or an NHS Trust and issued by a doctor, dentist, supplementary prescriber or independent nurse prescriber to enable a person to obtain pharmaceutical services and—

- (a) includes a prescription form provided and issued under equivalent arrangements having effect in England, Scotland or Northern Ireland; and
- (b) does not include a repeatable prescription;", and
- (iv) after the definition of "prescription form" insert the following definitions-

""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 Local Health Board and issued by a prescriber to enable a person to obtain pharmaceutical services, which is in the format specified in Part I of Schedule 1 to the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004, and which —

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

8.—(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 must, 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 £6.00, that is to say a charge of £12.00, per pair;
- (b) in respect of the supply of each other appliance and of each quantity of a drug, a charge of £6.00.

(1B) Where a charge is paid under paragraph (1A), the person making the payment must 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 (1A) where—
 - (a) there is an exemption under regulation 8 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 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—
 - (i) in cases falling within paragraph (1A), on the batch issue at the time that the drug or appliance is supplied,
 - (ii) 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 in accordance with paragraph 44 of Schedule 6 to the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004.
- (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)—
 - (a) after "paragraph (1)" insert "or paragraph (1A)"; and
 - (b) in the English text, omit "[dmb1/".

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(7)

31st March 2004

D. Elis-Thomas The Presiding Officer of the National Assembly

(7) 1998 c. 38.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the National Health Service (Pharmaceutical Services) Regulations 1992 (the "Pharmaceutical Regulations") and the National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001 (the "Charges Regulations").

The amendments establish a scheme within the National Health Service for repeat dispensing, which will enable prescribers to issue, and chemists to dispense, in accordance with, repeatable prescriptions.

Part 1 of these Regulations amends the Pharmaceutical Regulations. The main changes are as follows: regulation 2 of these Regulations inserts definitions into regulation 2 (interpretation); regulation 4 inserts regulation 16B specifying those chemists who are eligible to provide repeat dispensing services and how they should give notice of their intention to provide such services; regulation 6 amends Schedule 2 (terms of service for chemists), and makes provision regarding the dispensing of repeatable prescriptions. In particular, it inserts paragraph 3A into the Schedule, which makes specific provision for the dispensing of such prescriptions, for example, concerning the endorsement of such prescriptions by chemists, and the circumstances in which chemists must refuse to dispense such a prescription.

Part 2 of these Regulations amends the Charges Regulations. The main changes are as follows:

regulation 7 inserts definitions into regulation 2 and also amends regulation 2 to ensure that where more that 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 regulation 8 amends regulation 3 of the Charges Regulations, to clarify that the specified charges are payable on each batch issue, to require a person paying such a charge to sign a declaration that the charge has been paid, and to specify 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.