2005 No. 231

HEALTH AND PERSONAL SOCIAL SERVICES

Pharmaceutical Services and Charges for Drugs and Appliances (Amendment) Regulations (Northern Ireland) 2005

Made - - - - - *29th April 2005*

Coming into operation *1st May 2005*

The Department of Health, Social Services and Public Safety(**a**) in exercise of the powers conferred on it by Articles 63(1), (2), (2A) to (2D), 64, 98, 106(b) and 107(6) of, and Schedule 15 to the Health and Personal Social Services (Northern Ireland) Order 1972(**b**) and Article 10 of the Health and Medicines (Northern Ireland) Order 1988(**c**) and of all other powers enabling it in that behalf, and in conjunction with the Department of Finance and Personnel insofar as they relate to Pharmaceutical Services, and with the approval of the Department of Finance and Personnal insofar as they relate to Charges for Drugs and Appliances, and after consultation with such organisations as appear to it to be representative of the pharmaceutical profession as required by Article 63(3) of the Health and Personal Social Services (Northern Ireland) Order 1972, hereby make the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Pharmaceutical Services and Charges for Drugs and Appliances (Amendment) Regulations (Northern Ireland) 2005 and shall come into operation on 1st May 2005.

(2) In these Regulations –

(a) "the Pharmaceutical Regulations" means the Pharmaceutical Services Regulations (Northern Ireland) 1997(**c**).

(b) "the Charges for Drugs and Appliances Regulations" means the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997(**d**).

Amendment of the Pharmaceutical Services Regulations (Northern Ireland) 1997

2.—(1) The Pharmaceutical Services Regulations (Northern Ireland) 1997 are amended as follows.

(2) In regulation 2(1) (interpretation) –

(a) for the definition of "appropriate non-proprietary name" substitute –

(**a**) *See* S.I. 1999/283 (N.I.) Article 3(6)

(**b**) S.I. 1972/1265 (N.I. 14); relevant amending instruments are S.I. 1978/1907 (N.I. 26) Article 14; S.I. 1986/2023 (N.I. 20) Articles 5(1) and (2); S.I. 1986/2229 (N.I. 24); S.I. 1988/2249 (N.I. 24) Article 7; S.I. 1991/194 (N.I. 1) Articles 31(1) and (2), 34 and Part II of Schedule 5; S.I. 1992/2671 (N.I. 18) Article 3; S.I. 1997/1177 (N.I. 7) Article 29 and 2001 c. 3 (N.I.) Section 48

(**c**) S.R. 1997 No. 381 relevant amending instruments are S.I. 1988/2249 (N.I. 24); S.R. 1999 No. 254; S.R. 2001 No. 222; S.R. 2002 No. 92; S.R. 2002 No. 397 and S.R. 2003 No. 447

(**d**) S.R. 1997 No. 382 relevant amending instruments are S.R. 1998 No. 135; S.R. 1999 No. 166, S.R. 2000 No. 57 and S.R. 2004 No. 94

" "appropriate non-proprietary name" means a non-proprietary name which is not mentioned in Schedule 1 to the Prescription of Drugs Regulations or, except where the conditions in paragraph 40(2) of Schedule 5 to the GMS Regulations are satisfied, in Schedule 2 to the Prescription of Drugs Regulations;";

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

" "independent nurse prescriber" means a person –

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

(b) in respect of whom an annotation signifying that he is qualified to order drugs and appliances from –

(i) the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part IX(B) of the Drug Tariff, or

(ii) the Nurse Prescribers' Extended Formulary in Part IX(C) of the Drug Tariff,

is also recorded in that register;";

(c) for the definition of "patient" substitute –

" "patient" in relation to a GMS contract has the same meaning as in regulation 2 of the GMS Regulations (interpretation);";

(d) in the definition of "prescription form", at the end insert "and does not include a repeatable prescription";

(e) for the definition of "the Remission of Charges Regulations" substitute –

" "the Remission of Charges Regulations" mean the Travelling Expenses and Remission of Charges Regulations (Northern Ireland) 2004(**a**).";

(f) for the definition of "the charges regulations" substitute the following –

"the Charges for Drugs and Appliances Regulations" means "the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997.".

(g) after the definition of "the Remission of Charges Regulations", insert the following definitions –

" "repeat dispensing chemist" shall be construed in accordance with regulation 4A(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 the Agency and issued by a repeatable prescriber to enable a person to obtain pharmaceutical services, and which –

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

(b) indicates that the drugs or appliances ordered on that form may be provided more than once, and specifies the number of occasions on which they may be provided.";

(h) for the definition of "Scheduled drug" substitute –

" "Scheduled drug" means a drug or other substance specified in Schedule 1 to the Prescription of Drugs Regulations, or except where the conditions in paragraph 40(2) of Schedule 5 to the GMS Regulations are satisfied, Schedule 2 to the Prescription of Drugs Regulations;";

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

" "supplementary prescriber" means a person –

(a) whose name is registered in –

(i) the Nursing and Midwifery Register,

(ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954(**b**), or

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

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(**a**) S.R. 2004 No. 91
(**b**) 1954 c. 61
(**c**) S.I. 1976/1213 (N.I. 22)

(b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs and appliances as a supplementary prescriber.".

(j) omit the following definitions –

"doctor's list",

"doctor's terms of service",

"medical list",

"Medical Regulations",

"pilot scheme", and

"pilot scheme provider";

(k) insert each of the following definitions at the appropriate alphabetical place –

" "GMS contract" means a general medical services contract;

"the GMS regulations" means the Health and Personal Social Services (General Medical Services Contracts) Regulations (Northern Ireland) 2004(**a**);

"medical performers list" means a list of doctors prepared and published pursuant to regulation 4(1) and 5(1) of the Health and Personal Social Services (Performers Lists) Regulations (Northern Ireland 2004(**b**);

"Nursing and Midwifery Register" means the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001(**c**);

"patient list" means a list of patients kept by a Board in respect of a GMS contractor, in accordance with paragraph 14 of Schedule 5 to the GMS Regulations;

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

"the Prescription of Drugs Regulations" means the Health and Personal Services (General Medical Services Contracts) (Prescription of Drugs Etc) Regulations (Northern Ireland) 2004(**d**);

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

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

"relevant register" means –

(a) in relation to a nurse, the Nursing and Midwifery Register, and

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

"repeatable prescriber" means a prescriber who is –

(a) a GMS contractor who provides repeatable prescribing services under the terms of its contract which give effect to paragraph 39A(**e**) of Schedule 5 to the GMS Regulations;

(b) employed or engaged by a GMS contractor who provides repeatable prescribing services under the terms of a contract which give effect to paragraph 40 of Schedule 5 to the GMS Regulations.".

(3) For regulation 2(1B)(**f**) substitute –

"(1B) In these Regulations –

(**a**) S.R. 2004 No. 140
(**b**) S.R. 2004 No. 149
(**c**) S.I. 2002/253
(**d**) S.R. 2004 No. 142
(**e**) Paragraph 39A is inserted by S.R. 2005 No. 230
(**f**) Paragraph 1B was inserted by S.R. 2001 No. 222

(a) the term "pharmaceutical services", in relation to a doctor, means those services referred to in regulation 12; and

(b) the term "dispensing services" in relation to a doctor or to a GMS contractor means, any corresponding service provided, not as pharmaceutical services, but under the terms of a GMS contract which give effect to paragraphs 44 to 46 of Schedule 5 to the GMS Regulations.".

(4) After regulation 2(2) add –

"(3) For as long as there are in existence contracts entered into under Article 13 of the General Medical Services Transitional and Consequential Provisions (No. 1) (Northern Ireland) Order 2004(**a**) ("default contracts") in respect of such contracts any reference to a GMS contract shall be read as including a reference to a contract entered into under that Article, and any reference to a term of a GMS contract shall be read as including a reference to the equivalent term in the default contract.".

Insertion of Regulation 4A

3. After regulation 4 insert the following regulation –

"**Repeat dispensing services**

4A.—(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; and

(b) is included in the pharmaceutical list of a Board.

(3) A chemist who wishes to provide repeat dispensing services must notify the Board, 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 ten days after the date on which the notification specified in paragraph (3) is given.

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

Amendment of regulation 6 of the principal Regulations

4. In regulation 6 (pharmaceutical list) in paragraph (2)(b)(iii) after "pharmaceutical services" insert "(other than repeat dispensing services)".

Amendment of regulation 9

5. In regulation 9 (standards of, and payments for, drugs and appliances) –

(a) in paragraph (1)(g), after "supply of drugs and appliances" insert ", repeat dispensing services";

(b) after sub-paragraph (5) insert –

"(6) A chemist shall supply, in response to a request from the Department, within 30 days of the notification of the request, any information which the Department may

(**a**) S.R. 2004 No. 141

require for the purpose of conducting any enquiry into the prices, payments, fees, allowances and remuneration specified in paragraphs (1)(d) to (i).".

Amendment of regulation 10A

6. In regulation 10A (reward scheme) in paragraph (1) –

(a) after "paragraph 2(1)", in the first place it appears, insert "or paragraph 2(1A)";

(b) in sub-paragraph (a), for "immediately informed the Board of this action" substitute "informed the Board of this action as soon as practicable";

(c) for sub-paragraph (b) substitute –

"(b) he provided the drugs and medicines or listed appliances pursuant to paragraph (2)(1) or paragraph (2)(1A) 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 Board of this belief as soon as practicable,"; and

(d) at the end add "and the Board has established that the order referred to in this paragraph was not a genuine order for the person named on the prescription form.".

Omission of regulation 11

7. Regulation 11 (provision of pharmaceutical services for immediate treatment or personal administration) is omitted.

Amendment of regulation 12

8. For regulation 12 (arrangements for provision of pharmaceutical services by doctors) substitute –

"**12.**—(1) Where a patient satisfies a Board that he would have serious difficulty in obtaining any necessary drugs or appliances from a pharmacy by reason of distance or inadequacy of means of communication he may at any time request in writing that a doctor who falls within paragraph (2) provide him with pharmaceutical services.

(2) A doctor falls within this paragraph if he is –

(a) the GMS contractor, or

(b) engaged or employed by the GMS contractor on whose patient list the patient making the request is included.

(3) If a doctor so requested by a patient under paragraph (1) –

(a) applies to provide pharmaceutical services to the patient, and sends with his application the patient's request in writing, the Board shall make arrangements with him for the provision of such services by him; or

(b) does not so apply within 30 days, the Board may, subject to paragraph (6), require him to undertake such provision and shall give him notice in writing to that effect.

(4) An arrangement made by a Board under paragraph (3)(a) shall –

(a) have effect from the date of the patient's request in writing; and

(b) enable that doctor, any other doctor in his practice or any doctor who subsequently joined his practice to provide pharmaceutical services for the patient so long as the arrangement remains in effect.

(5) A Board shall not under paragraph (3)(b) require a doctor to provide pharmaceutical services to a person on the relevant patient list for that doctor if that doctor satisfies the Board, or on appeal, the Department that he does not normally provide pharmaceutical services under this regulation.

(6) A Board shall give a doctor reasonable notice –

(a) that it requires him to provide pharmaceutical services to any person; or

(b) subject to paragraph (7), that, where a person no longer satisfies the provisions of paragraph (1), the doctor shall discontinue the provision of pharmaceutical services to that person.

(7) A notice under paragraph (6)(b) shall not be given pending any appeal against the decision by a Board to postpone the making or termination of such arrangements.

(8) Notwithstanding paragraph (3), where a drug or appliance is one for which a doctor is entitled to an additional payment if he provides it, he may, with the consent of the patient, instead of providing it himself, order it by issuing a prescription to the patient in accordance with paragraph 39 of Schedule 5 to the GMS Regulations.

(9) Where under any provision of regulations revoked by, and not re-enacted in, these regulations an arrangement or requirement for a doctor to provide drugs or appliances to a patient was in effect immediately before these regulations came into operation, that arrangement or requirement shall have effect as though made under this regulation.

(10) A doctor who provides pharmaceutical services to some or all of the patients on the relevant patients list in accordance with this regulation may provide any necessary pharmaceutical services to a person whom the relevant GMS contractor has accepted as a temporary resident under paragraph 16 of Schedule 5 to the GMS Regulations.

(11) An appeal under paragraph (5) shall be made in writing within 30 days from and including the date on which notice of the decision was sent to the doctor and shall contain a concise statement of the grounds of appeal.

(12) The Department shall, on receipt of any notice of appeal under this regulation, send a copy of that notice to the Board and the relevant GMS contractor, and the Board and relevant GMS contractor may, within 30 days from and including the date on which the Department sent a copy of the notice of appeal, make representations in writing to it.

(13) The Department may determine an appeal pursuant to regulation (5) in such manner as it thinks fit.

(14) The Department shall, upon determination by it of an appeal under this regulation, give notice of it's decision in writing, together with the reasons for it, to the appellant, to the Board and to the relevant GMS contractor.".

Omission of regulation 12A

9. Regulation 12A (doctors who previously performed personal medical services) is omitted.

Amendment of regulation 12B

10. For regulation 12B(**a**) substitute –

"**12B.**—(1) A Board shall prepare and publish a list, to be called the dispensing doctor list, of the names of those doctors authorised or required by the Board under regulation 12 to provide pharmaceutical services to their patients and who are actually doing so.

(2) The dispensing doctor list shall indicate the address of the relevant GMS contractor from whose premises any doctor whose name is included performs primary medical services."

Amendment of regulation 12C

11. For regulation 12C(**a**) substitute –

"**12C.** A Board shall remove the name of a doctor from its dispensing doctor list when –

(a) the doctor has died; or

(**a**) Regulation 12A, 12B and 12C were inserted by S.R. 2001 No. 222

(b) the doctor is no longer performing primary medical services within the area of the Board; or

(c) more than 12 months have elapsed since the doctor last provided pharmaceutical services pursuant to the authorisation or requirement to provide such services given by the Board under regulation 12."

Amendment of regulation 16

12. In regulation 16(2)(b) (claims and overpayments) after the word "where" insert ", in the case of a chemist".

Amendment of Schedule 2

13.—(1) Schedule 2 is amended as follows.

(2) In paragraph 1 (incorporation of provisions) –

(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; and

"batch issue" means a form provided by the Agency and issued by the repeatable prescriber at the same time as a repeatable prescription to enable a chemist to receive payment for the provision of repeat dispensing services, and which –

(a) is generated by a computer and not signed by a repeatable prescriber;

(b) relates to a particular repeatable prescription and contains the same date as that prescription;

(c) is issued as one of a sequence of forms , the number of which is equal to the number of occasions on which the drugs and 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".

(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 2 (provision of pharmaceutical services) –

(a) for sub-paragraph (1) substitute –

"(1) Where any person presents on a prescription form –

(a) an order for drugs, not being Scheduled drugs, or appliances, not being restricted availability appliances, signed by a prescriber; or

(b) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, signed by, and endorsed on its face with the reference "SLS" by a prescriber; or

(c) an order for a restricted availability appliance, signed by and endorsed on its face with the reference "SLS" by a prescriber; or

(d) an order for listed drugs signed by a dentist or his deputy or assistant,

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

(b) after sub-paragraph (1) insert –

"(1A) Subject to sub-paragraph (2A) and paragraph 2A(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(**a**), other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations (Northern Ireland) 2002(**b**), signed by a repeatable prescriber,

(ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations (Northern Ireland) 2002, signed by and endorsed on its face with the reference "SLS" by a repeatable prescriber,

(iii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or

(iv) an order for a restricted availability appliance, signed by, and endorsed on its face with the reference "SLS" by, a repeatable prescriber,

and also presents an associated batch issue; or

(b) requests the provision of drugs and 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 (2), 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 (2A) –

(i) after "prescription form" insert "or repeatable prescription", and

(ii) after "paragraph 2(1)" insert "or paragraph 2(1A)";

(e) for sub-paragraph (2B) substitute –

"(2B) 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) of the Charges for Drugs and Appliances Regulations by virtue of either –

(i) entitlement to exemption under regulation 7(1) of the Charges for Drugs and Appliances Regulations, or

(ii) entitlement to remission of such charges under regulation 3 of the Remission of Charges Regulation,

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 for Drugs and Appliances Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) 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 (6) 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 (1A)";

(**a**) 1971 c. 38

(**b**) S.R. 2002 No. 1

(g) in sub-paragraph (7) –

(i) for "Misuse of Drugs Regulations (Northern Ireland) 1986" substitute "Misuse of Drugs Regulations (Northern Ireland) 2002";

(ii) for the words "a doctor, a dentist, a supplementary prescriber or an independent nurse prescriber" substitute "a prescriber or a dentist"; and

(iii) after "prescription form" insert "or repeatable prescription";

(h) in sub-paragraph (9) –

(i) for "Misuse of Drugs Regulations (Northern Ireland) 1986" substitute "Misuse of Drugs Regulations (Northern Ireland) 2002";

(ii) for the words "a doctor, dentist, supplementary prescriber or independent nurse prescriber" substitute "a prescriber or dentist"; and

(iii) after "prescription form" insert "or repeatable prescription";

(i) in sub-paragraph 10, for the words "the doctor, dentist, supplementary prescriber or independent nurse prescriber" substitute "the prescriber or dentist".

(j) in sub-paragraph (12) –

(i) for the words "a doctor, supplementary prescriber or independent nurse prescriber" substitute "prescriber"; and

(ii) after "prescription form" insert "repeatable prescription".

(k) in sub-paragraph (13), after "prescription form" insert "or repeatable prescription";

(l) in sub-paragraph (14), after "prescription form" insert "or repeatable prescription";

(m) in sub-paragraph (19), after "prescription form" insert "or repeatable prescription";

(n) after sub-paragraph (19) add –

"(20) 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.

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

(22) 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 2 (provision of pharmaceutical services), insert –

"**Provision of repeat dispensing services**

2A.—(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) 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 and 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 Agency.

(3) 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 and including 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.

(4) A repeat dispensing chemist shall destroy any batch issues relating to drugs and 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.

(5) 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.

(6) If a repeat dispensing chemist is not satisfied as mentioned in sub-paragraph (5), 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 prescriber, and

(ii) contact the prescriber 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 prescriber who issued that prescription of that fact as soon as is practicable.

(7) 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.

(8) 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 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 shall refuse to provide the drugs or appliances in question, and shall advise the person to contact the prescriber who issued the prescription or batch issue as soon as possible.

(9) 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.".

(6) In paragraph (5) (supply of drugs and fitting of appliances) in sub-paragraph (3) –

(a) after "paragraph 2(1)" insert "or paragraph 2(1A)"; and

(b) after "prescription" insert "or repeatable prescription".

(7) In paragraph 7 (charges for drugs) for sub-paragraph (2), substitute –

"(2) Where a chemist supplies a container in response to an order for drugs signed by a prescriber, or supplies an oxygen container or oxygen equipment, other than equipment specified in the Drug Tariff as not returnable to the chemist, the container and equipment shall remain the property of the chemist.".

(8) In paragraph 9 (remuneration of chemists), after sub-paragraph (2) insert –

"(2A) The Board shall make such payments, if any, as are provided for by the Drug Tariff (or by any determination made by virtue of regulation 9(2)) to chemists who provide repeat dispensing services.".

(9) For paragraph 13 substitute –

"**13.** Subject to paragraph 14(2), where a doctor is authorised or required by a Board under regulation 12 to provide drugs or appliances to a patient –

(a) he shall record an order for the provision of any drugs, or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with the term of a contract which gives effect to paragraph (39)(2) of Schedule 5 to the GMS Regulations or an equivalent provision applying in relation to that contract;

(b) he shall provide those drugs or appliances in a suitable container;

(c) he shall provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations only where the conditions in paragraph 40(2) of Schedule 5 to the GMS Regulations are satisfied; and

(d) he shall provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.".

(10) For paragraph 14(2) substitute –

"(2) Where a patient presents an order on a prescription form for drugs or listed appliances signed by a prescriber, or an order for a restricted availability appliance signed by and endorsed on its face with the reference "SLS" by a prescriber, to a doctor who is authorised or required by regulation 12 to provide drugs or appliances to that patient, the doctor may provide to the patient such of the drugs or appliances so ordered as he supplies in the normal course of his practice.".

(11) In paragraph 14A, in sub-paragraph (a) –

(a) for "regulation 3(1) of the Charges Regulations" substitute "regulation 4(1) of the Charges for Drugs and Appliances Regulations"; and

(b) for "sub-paragraph (d), (e) and (f) of regulation 7(1) of the Charges Regulations", substitute "sub-paragraph (a), (c), (d), (e), (f) or (g) of regulation 7(1) of the Charges for Drugs and Appliances Regulations or in respect of entitlement to remission by virtue of regulation 5(1)(e) or (2) of the Remission of Charges Regulations".

(12) For paragraph 16 substitute –

"**16.**—(1) The terms of a GMS contract giving effect to regulation 24 of, and Schedule 4 to the GMS Regulations (fees and charges) apply in respect of the provision of any drugs or appliances by a doctor as they apply in respect of prescriptions for drugs and appliances.

(2) Where a doctor who is authorised or required by a Board under regulation 12 to provide drugs or appliances provides a drug or appliance under pharmaceutical services –

(a) in accordance with this Part; and

(b) had the drug or appliance been provided by a contractor providing dispensing services under a GMS contract, the contractor would have been entitled to a payment in respect of that drug or appliance by virtue of directions given by the Department under Article 57C of the Order(**a**),

the Board shall credit him with the payment.".

(13) For paragraph 17 substitute –

(**a**) Article 57C was inserted by S.I. 2004/311 (N.I. 2)

"**17.**—(1) Where a doctor who is authorised or required by a Board under regulation 12 to provide drugs or appliances to a patient, or who otherwise provides pharmaceutical services is a GMS contractor, or is engaged or employed by a GMS contractor, the complaints procedure established in accordance with the terms of a GMS contract which give effect to paragraph 84 of Schedule 5 to the GMS Regulations, shall apply in relation to any matter reasonably connected with his provision of pharmaceutical services as it applies as respects to services provided under that contract or agreement.

(2) Accordingly, the term of the GMS contract which gives effect to paragraph 89 of Schedule 5 to the GMS Regulations also applies in relation to complaints about such matters.".

(14) Paragraph 18 is omitted.

Amendment of the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997

14. 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 the Agency 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, 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" substitute the following definitions –

" "prescription form" means a form provided by the Agency 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 England, Scotland and Wales; and

(b) does not include a repeatable prescription;

"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 the Agency and issued by a doctor to enable a person to obtain pharmaceutical services, 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; and

(c) 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 of the principal Regulations

15.—(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 £6·50, that is to say a charge of £13·00 per pair;

(b) in respect of the supply of each other appliance and of each quantity of drug, a charge of £6·50.

(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, or

(ii) in all other cases, on a 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, or

(ii) in all other cases, on the prescription form.".

(5) In paragraph (4) –

(a) after "prescription form" insert "or repeatable prescription"; and

(b) after "paragraph (1)" insert "or paragraph (1A)".

(6) In paragraph (5), after "paragraph (1)" insert "or paragraph (1A)".

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 29th April 2005.

(L.S.) *Deirdre Kenny*

A senior officer of the Department of Health, Social Services and Public Safety

Sealed with the Official Seal of the Department of Finance and Personnel insofar as the foregoing regulations relate to pharmaceutical services on 29th April 2005.

(L.S.) *Mary McIvor*

A senior officer of the Department of Finance and Personnel

The Department of Finance and Personnel hereby approves the foregoing Regulations insofar as they relate to Charges for Drugs and Appliances.

Sealed with the Official Seal of the Department of Finance and Personnel on 29th April 2005.

(L.S.) *Mary McIvor*

A senior officer of the Department of Finance and Personnel

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations further amend the Pharmaceutical Services Regulations (Northern Ireland) 1997 and the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997 to establish a scheme for repeat dispensing, which involves doctors issuing, and chemists dispensing in accordance with, repeatable prescriptions.

Regulation 2 inserts definitions into regulation 2 of the Pharmaceutical Services Regulations.

Regulation 3 adds regulation 4A to the Pharmaceutical Services Regulations, specifying those chemists who are eligible to provide repeat dispensing services and how they should notify the Board that they wish to do so.

Regulation 13 amends Schedule 2 to the Pharmaceutical Services Regulations (chemists' terms of service), and makes provision regarding the dispensing of repeat prescriptions. In particular, it inserts paragraph 2A into that Schedule which makes specific provision for the dispensing of such prescriptions (regulation 13(5)), 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, 6, 7, 8, 9, 10, 11, and 12 of these regulations make further minor amendments to the Pharmaceutical Services Regulations unconnected with repeat dispensing.

Regulation 14 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.

Regulation 15 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.

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