

2003 No. 443

NATIONAL HEALTH SERVICE

**The National Health Service (General Medical Services)
(Scotland) Amendment (No. 3) Regulations 2003**

<i>Made</i>	<i>17th September 2003</i>
<i>Laid before the Scottish Parliament</i>	<i>19th September 2003</i>
<i>Coming into force</i>	<i>10th October 2003</i>

The Scottish Ministers, in exercise of the powers conferred by sections 2(5), 19, 28(1), 105(7) and 108(1) of the National Health Service (Scotland) Act 1978(a), and of all other powers enabling them in that behalf, hereby make the following Regulations:

PART I
INTRODUCTORY

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the National Health Service (General Medical Services) (Scotland) Amendment (No. 3) Regulations 2003 and, shall come into force on 10th October 2003.

(2) In these Regulations, “the principal Regulations” means the National Health Service (General Medical Services) (Scotland) Regulations 1995(b).

(a) 1978 c.29; section 2(5) was amended by the National Health Service and Community Care Act 1990 (c.19) (“the 1990 Act”), Schedule 9, paragraph 19; section 19 was amended by the Health Services Act 1980 (c.53) (“the 1980 Act”), section 7, by the Health and Social Services and Social Security Adjudications Act 1983 (c.41) (“the 1983 Act”), Schedule 7, paragraph 2, by the Medical Act 1983 (c.54), Schedule 5, paragraph 17(a), by the 1990 Act, section 37, by the Medical (Professional Performance) Act 1995 (c.51), Schedule, paragraph 29(a), and by the National Health Service (Primary Care) Act 1997 (c.46), Schedule 2, Part I, paragraph 39 and Schedule 3, Part I, and is to be read with the Health and Medicines Act 1988 (c.49), section 17; section 28(1) was amended by the National Health Service (Amendment) Act 1986 (c.66), section 3(4); section 105(7) which contains provisions relating to the making of Regulations, was amended by the 1980 Act, Schedule 6, paragraph 5 and Schedule 7, by the 1983 Act, Schedule 9, Part I, paragraph 24 and by the Health Act 1999 (c.8), Schedule 4, paragraph 60; section 108(1) contains a definition of “regulations” relevant to the exercise of the statutory powers under which these Regulations are made. The functions of the Secretary of State were transferred to the Scottish Ministers by virtue of section 53 of the Scotland Act 1998 (c.46).

(b) S.I. 1995/416; relevant amending instruments are S.I. 1995/3199, 1996/1504, 1997/943, 1998/4 and 660, 1999/749 and 1620 and S.S.I. 1999/54 and 2002/111.

PART II

AMENDMENTS RELATING TO PRESCRIBING BY NURSES AND PHARMACISTS

Amendment of regulation 2 of the principal Regulations

2. In regulation 2 of the principal Regulations (interpretation)–
- (a) in paragraph (1) omit the definition of “nurse prescriber”(a); and
 - (b) omit paragraph (1A)(b).

Amendment of Schedule 1 to the principal Regulations

3. In Schedule 1 to the principal Regulations (terms of service for doctors)–
- (a) in paragraph 1–
 - (i) after sub-paragraph (a) insert–
 - “(aa) “independent nurse prescriber” means–
 - (i) a person whose name is registered–
 - (aaA) in Part 1 or 12 of the nurses’ and midwives’ professional register and has a district nurse qualification additionally recorded in the nurses’ and midwives’ professional register pursuant to rule 11 of the Nurses, Midwives and Health Visitors Rules 1983(c); or
 - (bbB) in Part 11 of the nurses’ and midwives’ professional register as a health visitor,
and against whose name is recorded in the nurses’ and midwives’ professional register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Nurse Prescribers’ Formulary for Community Nurses and Health Visitors in Part 8B of the Drug Tariff(d); or
 - (ii) a person–
 - (aaA) whose name is registered in parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the nurses’ and midwives’ professional register; and
 - (bbB) against whose name is recorded in the nurses’ and midwives’ professional register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Nurse Prescribers’ Extended Formulary in Part 8C of the Drug Tariff;
 - (ab) “licensing authority” shall be construed in accordance with section 6(3) of the Medicines Act 1968(e);
 - (ac) “nurses’ and midwives’ professional register” means the register maintained by the Nursing and Midwifery Council pursuant to paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001(f);”;
 - (ii) after paragraph (b) insert–
 - “(ba) “the POM Order” means the Prescription Only Medicines (Human Use) Order 1997(g);”;
 - (iii) in paragraph (d) for “a nurse prescriber” substitute “a supplementary prescriber or an independent nurse prescriber”;
 - (iv) number the definition of “restricted availability appliance”(h) as paragraph (db);

(a) The definition of “nurse prescriber” was inserted by S.I. 1996/1504. References to “nurse prescriber” were inserted by S.I. 1996/1504 and 1999/1620.

(b) Paragraph (1A) was inserted by S.I. 1996/1504.

(c) Approved by S.I. 1983/873 and set out in the Schedule thereto; there are no relevant amending instruments.

(d) Copies of the Drug Tariff are available for inspection at the offices of Health Boards and primary care NHS trusts in accordance with S.I. 1995/414 as amended by S.S.I. 1999/57.

(e) 1968 c.67.

(f) S.I. 2002/253.

(g) S.I. 1997/1830; the relevant amending instruments are S.I. 2002/549 and 2003/696.

(h) The definition of “restricted availability appliance” was inserted by S.S.I. 2002/111.

- (v) after paragraph (d) insert–
“(da) “prescription only medicine” means a medicine referred to in article 3 of the POM Order (medicinal products on prescription only);”;
- (vi) after paragraph (db) insert–
“(dc) “supplementary prescriber” means a person whose name is registered in–
(i) Parts 1, 3, 5, 8, 10, 11, 12, 13, 14, or 15 of the nurses’ and midwives’ professional register;
(ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954(a); or
(iii) the register maintained in pursuance of articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(b),
and against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber;”;
- (b) In paragraph 29A(1) and (2)(c) for the words “a nurse prescriber”, at each place where they occur, substitute “a supplementary prescriber or an independent nurse prescriber”.
- (c) In paragraph 29B(1)(d) for the words “a nurse prescriber” substitute “a supplementary prescriber or an independent nurse prescriber”.
- (d) After paragraph 29B, insert–
“**29C.**—(1) Where, after 10th October 2003, a doctor employs a supplementary prescriber and that person’s functions include prescribing, the doctor shall have arrangements in place to secure that that person will only–
(a) give a prescription for a prescription only medicine;
(b) administer a prescription only medicine for parenteral administration; or
(c) give directions for the administration of a prescription only medicine for parenteral administration,
as a supplementary prescriber under the conditions set out in sub-paragraph (2).
(2) The conditions referred to in sub-paragraph (1) are that–
(a) the person satisfies the applicable conditions set out in article 3B(3)(e) of the POM Order (prescribing and administration by supplementary prescribers), unless those conditions do not apply by virtue of any of the exemptions set out in the subsequent provisions of that Order;
(b) the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971(f);
(c) the medicine is not specified in Schedule 10 (drugs and other substances not to be supplied by general medical practitioners or prescribed for supply under pharmaceutical services);
(d) the medicine is not specified in an entry in column 1 of Schedule 11 (drugs to be supplied by general medical practitioners or prescribed for supply under pharmaceutical services only in certain circumstances), unless–
(i) the patient is a person of a description mentioned in column 2 of that entry;
(ii) the medicine is prescribed for that patient only for the purposes specified in column 3 of that entry; and
(iii) if he is giving a prescription, he endorses the face of the form with the reference “SLS”.
(3) Where, after 10th October 2003, a doctor employs a supplementary prescriber and that person’s functions include prescribing, the doctor shall have arrangements in place to secure that that person will only give a prescription for–
(a) an appliance; or
(b) a medicine which is not a prescription only medicine,
as a supplementary prescriber under the conditions set out in sub-paragraph (4).

(a) 1954 c.61.

(b) S.I. 1976/1213.

(c) Paragraph 29A was inserted by S.I. 1996/1504.

(d) Paragraph 29B was inserted by S.I. 1999/1620 and amended by S.S.I. 1999/54.

(e) Article 3B was inserted by S.I. 2003/696.

(f) 1971 c.38.

- (4) The conditions referred to in sub-paragraph (3) are that–
- (a) he acts in accordance with a clinical management plan (which may be amended from time to time) which is in effect at the time he acts, which has been agreed by the patient to whom the plan relates, the doctor or dentist who is party to the plan and any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan, and which contains the following particulars:–
 - (i) the name of the patient to whom the plan relates;
 - (ii) the illness or conditions which may be treated by the supplementary prescriber;
 - (iii) the date on which the plan is to take effect, and when it is to be reviewed by the doctor or dentist who is a party to the plan;
 - (iv) reference to the class or description of medicines or types of appliances which may be prescribed or administered under the plan;
 - (v) any restrictions or limitations as to the strength or dose of any medicine which may be prescribed or administered under the plan, and any period of administration or use of any medicine or appliance which may be prescribed or administered under the plan;
 - (vi) relevant warnings about known sensitivities of the patient to, or known difficulties of the patient with, particular medicines or appliances;
 - (vii) the arrangements for notification of–
 - (aa) suspected or known adverse reactions to any medicine which may be prescribed or administered under the plan, and suspected or known adverse reactions to any other medicine taken at the same time as any medicine prescribed or administered under the plan; and
 - (bb) incidents occurring with the appliance which might lead, might have led or has led to the death or serious deterioration of state of health of the patient; and
 - (viii) the circumstances in which the supplementary prescriber should refer to, or seek the advice of, the doctor or dentist who is a party to the plan;
 - (b) he has access to the health records of the patient to whom the plan relates which are used by any doctor or dentist who is a party to the plan;
 - (c) if it is a prescription for a medicine, the medicine is not a controlled drug within the meaning of the Misuse of Drugs Act 1971;
 - (d) if it is a prescription for a medicine, the medicine is not specified in Schedule 10 (drugs and other substances not to be supplied by general medical practitioners or prescribed for supply under pharmaceutical services);
 - (e) if it is a prescription for a medicine, the medicine is not specified in an entry in column 1 of Schedule 11 (drugs to be supplied by general medical practitioners or prescribed for supply under pharmaceutical services only in certain circumstances), unless–
 - (i) the patient is a person of a description mentioned in column 2 of that entry;
 - (ii) the medicine is prescribed for that patient only for the purposes specified in column 3 of that entry; and
 - (iii) if he is giving a prescription, he endorses the face of the form with the reference “SLS”;
 - (f) if it is a prescription for a medicine–
 - (i) the medicine is the subject of a product licence, a marketing authorisation or a homeopathic certificate of registration granted by the licensing authority or the European Commission; or
 - (ii) the use of the medicine is for the purposes of a clinical trial, and–
 - (aa) that trial is the subject of a clinical trial certificate issued in accordance with the Medicines Act 1968(a); or
 - (bb) a clinical trial certificate is not needed in respect of that trial by virtue of any exemption conferred by or under that Act;
 - (g) if it is a prescription for an appliance, the appliance is listed in the Drug Tariff; and

(a) 1968 c.67.

- (h) if it is a prescription for a restricted availability appliance—
 - (i) the patient is a person of a description mentioned in the entry in the Drug Tariff in respect of that appliance;
 - (ii) the appliance is prescribed only for the purposes specified in respect of that person in that entry; and
 - (iii) when giving the prescription, he endorses the face of the form with the reference “SLS”.

PART III
OTHER AMENDMENTS

Amendment of regulation 27 of the principal Regulations

- 4. In regulation 27 of the principal Regulations (doctors’ lists) in paragraph (3)—
 - (a) omit sub-paragraph (e) and “or” at the end of sub-paragraph (d); and
 - (b) for “departure, enlistment or imprisonment” substitute “departure or enlistment”.

Other Amendments to Schedule 1 to the principal Regulations

- 5. After paragraph 20A(a) of Schedule 1 to the principal Regulations insert—

“**20B**—(1) After 10th October 2003, subject to sub-paragraphs (2) and (3), a doctor shall not engage as a deputy, or employ as an assistant, any doctor unless—

 - (a) the deputy or assistant has provided two clinical references, relating to two recent posts (which may include any current post) as a doctor which lasted for at least three months without a significant break, or where this is not possible, a full explanation and alternative referees; and
 - (b) the doctor has checked and is satisfied with the doctor’s references.

(2) Where a doctor is urgently needed as a deputy, and it is not possible to obtain and check the references in accordance with paragraph (1)(b) before engaging him, he may be engaged on a temporary basis for a single period of up to 14 days whilst his references are checked and considered, and for an additional single period of a further seven days if the doctor believes the person supplying those references is ill, on holiday or otherwise temporarily unavailable.

(3) Where a doctor uses the same doctor as a deputy on more than one occasion within a period of three months, he may rely on the references provided on the first occasion, provided that those references are not more than twelve months old.”.

MALCOLM CHISHOLM
A member of the Scottish Executive

St. Andrew’s House,
Edinburgh
17th September 2003

(a) Paragraph 20A was inserted by S.I. 1998/660.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the National Health Service (General Medical Services) (Scotland) Regulations 1995 (“the principal Regulations”) which regulate the terms on which doctors provide general medical services under the National Health Service (Scotland) Act 1978 (“the 1978 Act”).

Part II makes changes to the principal Regulations arising out of the designation of a new category of prescriber of medicines and appliances for human use. Under amendments to the Prescription Only Medicines (Human Use) Order 1997 which came into force on 4th April 2003, “supplementary prescribers”, who are appropriately qualified nurses and pharmacists, have been given new rights to prescribe prescription only medicines under an agreed clinical management plan for an individual patient. These “supplementary prescribers” will also be qualified to prescribe other medicines and appliances under such plans.

In particular–

regulation 2 deletes the definition of “nurse prescriber” in the principal Regulations;

regulation 3(a) inserts new definitions of “supplementary prescriber” and “independent nurse prescriber”, and other related definitions, to differentiate more clearly between the different categories of nurses who may prescribe;

regulation 3(b) and (c) amends the rules relating to the supply by doctors of drugs and appliances on prescription forms signed by nurse prescribers to relate both to supplementary prescribers and to nurses who are independent nurse prescribers;

regulation 3(d) requires doctors who employ supplementary prescribers to have arrangements in place to ensure that the supplementary prescribers they employ comply with the regime of control relating to supplementary prescribing.

Part III makes other unrelated changes to the principal Regulations.

Regulation 4 removes the requirement on Health Boards and primary care NHS trusts to delete from the list of patients in its area, for whom each doctor is responsible, the name of a person serving a prison sentence or sentences totalling in aggregate more than two years.

Regulation 5 introduces a requirement on doctors employing deputies or assistants to obtain and check clinical references before engaging them.

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