S T A T U T O R Y I N S T R U M E N T S

2003 No. 699

NATIONAL HEALTH SERVICE, ENGLAND

The National Health Service (Amendments Relating to Prescribing by Nurses and Pharmacists etc.) (England) Regulations 2003

Made - - - -	*13th March 2003*
Laid before Parliament	*14th March 2003*
Coming into force	*4th April 2003*

The Secretary of State for Health, in exercise of the powers conferred upon him by sections 29, 41, 42, 43, 77 and 126(4) of the National Health Service Act 1977**(a)**, and all other powers enabling him in that behalf, hereby makes the following Regulations:

Citation, commencement and application

1.—(1) These Regulations may be cited as the National Health Service (Amendments Relating to Prescribing by Nurses and Pharmacists etc.) (England) Regulations 2003 and shall come into force on 4th April 2003.

(2) These Regulations apply to England only.

Amendment of the National Health Service (Pharmaceutical Services) Regulations 1992

2.—(1) The National Health Service (Pharmaceutical Services) Regulations 1992**(b)** are amended as follows.

(a) 1977 c.49; section 29 was extended by the Health and Medicines Act 1988 (c.49) ("the 1988 Act"), section 17 and amended by: the Health Services Act 1980 (c.53) ("the 1980 Act"), sections 1 and 7 and Schedule 1, paragraph 42(b); the Health and Social Services and Social Security Adjudications Act 1983 (c.41), Schedule 6, paragraph 2; the Medical Act 1983 (c.54), section 56(1) and Schedule 5, paragraph 16(a); S.I. 1985/39, article 7; the Health Authorities Act 1995 (c.17) ("the 1995 Act"), Schedule 1, paragraph 18; the Medical (Professional Performance) Act 1995 (c.51), Schedule 4, paragraph 28; the National Health Service (Primary Care) Act 1997 (c.46) ("the 1997 Act"), Schedule 2, paragraphs 3 and 8, and Part I of Schedule 3; the Health and Social Care Act 2001 (c.15) ("the 2001 Act"), section 17 and Schedule 6 (although these amendments are not yet fully in force, *see* article 2(3) of S.I. 2001/3738); and the National Health Service Reform and Health Care Professions Act 2002 (c.17) ("the 2002 Act"), Schedule 2, paragraph 3. Section 41 was substituted by the 2001 Act, section 42(1), and amended by the 2002 Act, Schedule 2, paragraph 13. Section 42 was substituted by the National Health Service Amendment Act 1986 (c.66), section 31, then extended by the 1988 Act, section 17, and amended by: S.I. 1987/2202, article 4; the National Health Service and Community Care Act 1990 (c.19) ("the 1990 Act"), section 12(3); the 1995 Act, Schedule 1, paragraph 30; the 2001 Act, section 43(2) to (4); and the 2002 Act, Schedule 2, paragraph 16. Section 43 was amended by: the 1980 Act, sections 1 and 21(2), and Schedule 1, paragraph 55; S.I. 1985/39, article 7(15); the 1990 Act, Schedule 9, paragraph 18(2); the 1995 Act, Schedule 1, paragraph 31; the 1997 Act, section 29(1) and Schedule 2, paragraph 14; the 2001 Act, sections 42(2) and 43(5); and the 2002 Act, Schedule 2, paragraph 17. Section 126(4) was amended by the 1990 Act, section 65(2). *See* section 128(1) of the National Health Service Act 1977 as amended by the 1990 Act, section 26(2)(g) and (i), for definitions of "prescribed" and "regulations" which are relevant to the powers being exercised in the making of these Regulations. As regards Wales, these functions of the Secretary of State under the 1977 Act were transferred to the National Assembly for Wales by virtue of article 2 of, and Schedule 1 to, the National Assembly for Wales (Transfer of Functions) Order 1999, S.I. 1999/672, as amended by section 66(5) of the Health Act 1999 (c.8) and as read with section 40(1) of the 2002 Act.

(b) S.I. 1992/662; the relevant amending instruments are S.I. 1993/2451, 1994/2402, 1995/644, 1996/698, 1998/681, 1999/696 and 2563, 2000/593, 2001/2888, and 2002/551, 2016, 2469 and 2861.

(2) In regulation 2(1) (interpretation)—

(a) insert each of the following definitions at the appropriate alphabetical place—

" "independent nurse prescriber" means—

(a) a person whose name is registered—

(i) 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**(a)**, or

(ii) 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 District Nurses and Health Visitors in Part XVIIB(i) of the Drug Tariff; or

(b) a person—

(i) 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

(ii) 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 XVIIB(ii) of the Drug Tariff;";

" "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**(b)**;"; and

" "supplementary prescriber" means a person whose name is registered in—

(a) Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the nurses and midwives' professional register;

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

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

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 the definition of "prescription form", for "dentist or nurse prescriber" substitute "dentist, supplementary prescriber or independent nurse prescriber"; and

(c) the definition of "nurse prescriber" is omitted.

(3) In Schedule 2 (terms of service)—

(a) in paragraph 3—

(i) in sub-paragraph (1)(a) and (b), after "doctor", at both places where it occurs, insert "or a supplementary prescriber",

(ii) in sub-paragraph (1)(d) and (e), for "a nurse prescriber" at both places where it occurs, substitute "an independent nurse prescriber",

(iii) in sub-paragraph (4), for "dentist or a nurse prescriber" substitute "dentist, a supplementary prescriber or an independent nurse prescriber",

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(a) Approved by S.I. 1983/873 and set out in the Schedule thereto; there are no relevant amending instruments.
(b) S.I. 2002/253.
(c) 1954 c.61.
(d) S.I. 1976/1213 (N.I. 22).

(iv) in sub-paragraphs (6) and (7), for "dentist or nurse prescriber" substitute "dentist, supplementary prescriber or independent nurse prescriber", and

(v) in sub-paragraph (9), for "doctor or nurse prescriber", at both places where it occurs, substitute "doctor, supplementary prescriber or independent nurse prescriber";

(b) in paragraph 7(2), for "Regulations or by a nurse prescriber" substitute "Regulations, or by a supplementary prescriber or an independent nurse prescriber,"; and

(c) in paragraphs 11A and 11B, before "a nurse prescriber" at each place where it occurs, insert "an independent prescriber".

Amendment of the National Health Service (General Medical Services) Regulations 1992

3.—(1) The National Health Service (General Medical Services) Regulations 1992**(a)** are amended as follows.

(2) In regulation 2(1) (interpretation) the definition of "nurse prescriber" is omitted.

(3) In Schedule 2 (terms of service)—

(a) in paragraph 1, insert each of the following definitions at the appropriate alphabetical place—

""independent nurse prescriber" means—

(a) a person whose name is registered—

(i) in Part 1 or 12 of the professional register and has a district nurse qualification additionally recorded in the professional register pursuant to rule 11 of the Nurses, Midwives and Health Visitors Rules 1983, or

(ii) in Part 11 of the professional register as a health visitor,

and against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVIIB(i) of the Drug Tariff; or

(b) a person—

(i) whose name is registered in Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the professional register, and

(ii) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Extended Formulary in Part XVIIB(ii) of the Drug Tariff;";

""licensing authority" shall be construed in accordance with section 6(3) of the Medicines Act 1968**(b)**;";

""the POM Order" means the Prescription Only Medicines (Human Use) Order 1997**(c)**;";

""prescription only medicine" means a medicine referred to in article 3 of the POM Order (medicinal products on prescription only);"; and

""supplementary prescriber" means a person whose name is registered in—

(a) Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the professional register;

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

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

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(a) S.I. 1992/635; the relevant amending instruments are S.I. 1992/2412, 1993/2421, 1994/2620, 1995/3093, 1997/981, 1998/682 and 2838, 1999/326 and 1627, 2000/1645, 2001/1178, 3386 and 3742, 2002/554, 881, 1768, 1920 and 2469, and 2003/26.

(b) 1968 c.67.

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

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 28A(1) and (2), for "a nurse prescriber", at each place where it occurs, substitute "a nurse who is a supplementary prescriber or an independent nurse prescriber"; and

(c) after paragraph 28A, insert the following paragraph—

"**28B.**—(1) Where 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) 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**(a)**;

(c) the medicine is not specified in Schedule 10 to the Medical Regulations (drugs and other substances not to be prescribed for supply under pharmaceutical services);

(d) the medicine is not specified in an entry in column 1 of Schedule 11 to the Medical Regulations (drugs to be prescribed 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 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).

(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 a 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,

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(a) 1971 c.38.

(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,

(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 to the Medical Regulations (drugs and other substances not to be 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 to the Medical Regulations (drugs to be prescribed 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) when giving the 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 authorization 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, 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 Part IX of the Drug Tariff; and

(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 Part IX of 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".".

(4) In Schedule 11 (drugs to be prescribed under pharmaceutical services only in certain circumstances), after "Tadalafil (Cialis)" in columns 1 and 2, insert in each of those columns ", Vardenafil (Levitra)".

Amendment of the National Health Service (Charges for Drugs and Appliances) Regulations 2000

4.—(1) The National Health Service (Charges for Drugs and Appliances) Regulations 2000**(a)** are amended as follows.

(2) In regulation 2(1) (interpretation)—

(a) insert each of the following definitions at the appropriate alphabetical place—

" "Drug Tariff" means the statement compiled, published and amended from time to time by the Secretary of State pursuant to regulation 18 of the National Health Service (Pharmaceutical Services) Regulations 1992 (standards of, and payments for, drugs and appliances);";

" "independent nurse prescriber" means—

(a) a person whose name is registered—

(i) 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, or

(ii) 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 District Nurses and Health Visitors in Part XVIIB(i) of the Drug Tariff; or

(b) a person—

(i) 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

(ii) 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 XVIIB(ii) of the Drug Tariff;";

" "nurses and midwives' professional registers" means the register maintained by the Nursing and Midwifery Council pursuant to paragraph 10 of Schedule 2 to the Nursing and Midwifery Order 2001;"; and

(a) S.I. 2000/620; the relevant amending instruments are S.I. 2000/3189, 2001/2887, and 2002/548 and 2352.

" "supplementary prescriber" means a person whose name is registered in—

(a) Parts 1, 3, 5, 8, 10, 11, 12, 13, 14 or 15 of the nurses and midwives' professional register;

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

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

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 the definition of "prescription form", for "dentist or nurse prescriber" substitute "dentist, supplementary prescriber or independent nurse prescriber"; and

(c) the definition of "nurse prescriber" is omitted.

(3) In regulation 6(1) (supply of drugs and appliances at Walk-in-Centres), for "doctor or nurse prescriber" substitute "doctor, supplementary prescriber or independent nurse prescriber".

Signed by authority of the Secretary of State for Health

Hunt
Parliamentary Under Secretary of State,
Department of Health

13th March 2003

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make changes to Regulations relating to pharmaceutical services, general medical services and charges for drugs and appliances, arising out of the designation of a new category of prescriber of medicines and appliances for human use.

Regulation 2 amends the National Health Service (Pharmaceutical Services) Regulations 1992 ("the Pharmaceutical Services Regulations"). Under amendments to the Prescription Only Medicines (Human Use) Order 1997 which are coming into force at the same time as these Regulations, "supplementary prescribers", who are appropriately qualified nurses and pharmacists, are being 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. The pre-existing category of "nurse prescriber" in the Pharmaceutical Services Regulations is renamed as "independent nurse prescriber" to differentiate more clearly between the different categories of nurses who may prescribe. Amendments are made to the terms of service provisions in Schedule 2 to the Pharmaceutical Services Regulations to ensure that chemists may dispense against prescriptions of supplementary prescribers, and to update the other provisions of that Schedule so that that where reference is made to orders or prescriptions for medicines or appliances, the provisions reflect the possibility that the order or prescription may now come from a supplementary prescriber.

Regulation 3 makes changes to the National Health Service (General Medical Services) Regulations 1992. As a result, the existing rules relating to the employment by doctors of "nurse prescribers" will now relate both to nurses who are supplementary prescribers and, as before, to nurses who are independent nurse prescribers. Also, doctors who employ supplementary prescribers are required to have arrangements in place to ensure that the supplementary prescribers they employ comply with the regime of control relating to supplementary prescribing. A change is also made to the list of drugs that may only be prescribed in certain circumstances in Schedule 11 to those Regulations. As a consequence Levitra may only be prescribed under the National Health Service in the circumstances specified in that Schedule.

Amendments arising out of the introduction of supplementary prescribing are also made to the National Health Service (Charges for Drugs and Appliances) Regulations 2000. These follow on from the fact that supplementary prescribers may now be issuing prescription forms, as well as potentially taking responsibility for prescribing for patients in Walk-in-Centres, if the supplementary prescribers are parties to a clinical management plan for that patient.

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