WELSH STATUTORY INSTRUMENTS

2003 No. 2624 (W.252)

NATIONAL HEALTH SERVICE, WALES

The National Health Service (Amendments concerning Supplementary and Independent Nurse Prescribing) (Wales) Regulations 2003

Made - - - -	*8th October 2003*
Coming into force - -	*10th October 2003*

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

Citation, commencement, interpretation and application

1.—(1) These Regulations may be cited as the National Health Service (Amendments concerning Supplementary and Independent Nurse Prescribing) (Wales) Regulations 2003.

(2) These Regulations come into force on 10th October 2003.

(3) These Regulations apply to Wales only.

(**1**) 1977 c. 49; *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 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 126(4) was amended by the 1990 Act, section 65(2) and the 1999 Act , Schedule 4, paragraph 37(6).
Section 41 was amended by the Act 1980, sections1 and 20(1) and Schedule 1, paragraph 53 and Schedule 7; by SI 1985/39, article 7(13); by the 1990 Act, Schedule 9, paragraph 18(1) and Schedule 10; by the Medicinal Products: Prescription by Nurses etc. Act 1992 (c. 28), section 2; by the 1995 Act, Schedule 1, paragraph 29 and by the 1997 Act, Schedule 2, paragraph 13.
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.
The functions of the Secretary of State under sections 29 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(5).

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

2.—(1) The National Health Service (Pharmaceutical Services) Regulations 1992(**2**) are amended in accordance with the following provisions of this regulation.

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

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

""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(**3**), 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 or she is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVII B(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 or she 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(**4**);" 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(**5**); or

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

and against whose name is recorded in the relevant register an annotation signifying that he or she 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.

(**2**) S.I.1992/662; the relevant amending instruments are S.I.1996/698, 1998/681, 1999/696, 2001/1396 (W.91) and 2002/3189 (W.305).
(**3**) Approved by S.I.1983/873 and set out in the Schedule thereto; there are no relevant amending instruments.
(**4**) S.I.2001/253.
(**5**) 1954 c. 61.
(**6**) S.I.1976/1213.

(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 nurse prescriber" substitute "dentist, a supplementary prescriber or an independent nurse prescriber",

(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" 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 nurse prescriber or".

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

3.—(1) The National Health Service (General Medical Services) Regulations 1992(**7**) are amended in accordance with the following provisions of this regulation.

(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 in the appropriate place in the alphabetical order—

""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 or she is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVII B(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 or she is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Extended Formulary in Part XVIIB (ii) of the Drug Tariff;";

(**7**) S.I.1992/635; the relevant amending instruments are S.I.1992/2412, 1993/2421, 1994/2620, 1995/3093, 1998/682 and 2838, 1999/326, 2001/833 (W.35), 2002/916 (W.104) and 1896 (W.197) and 2003/784 (W.95).

""licensing authority" shall be construed in accordance with section 6(3) of the Medicines Act 1968(**8**);";

""the POM Order" means the Prescription Only Medicines (Human Use) Order 1997(**9**);";

""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,

and against whose name is recorded in the relevant register an annotation signifying that he or she 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 ensure 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(**10**);

(c) the medicine is not specified in Schedule 10 (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(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,

(**8**) 1968 c. 67.
(**9**) S.I.1997/1830; the relevant amending instruments are S.I.2000/549 and 2003/696.
(**10**) 1971 c. 38.

(ii) the medicine is prescribed for that patient only for the purposes specified in column 3 of that entry, and

(iii) if the prescriber is giving a prescription, he or she 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 ensure that that person will only give a prescription for —

(a) an appliance; or

(b) a medicine that 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 or she 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 that 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,

(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 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 prescribed 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 or she 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 purpose 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 or she endorses the face of the form with the reference "SLS".".

Amendment of the National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001

4.—(1) The National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001(**11**) are amended in accordance with the following provisions of this regulation.

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

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

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

""independent nurse prescriber" ("*nyrs sy'n rhagnodi'n annibynnol*") means—

(a) a person whose name is registered—

(**11**) S.I.2001/1358 to which there are no relevant amending instruments.

(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 or she is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVII B(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 or she 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" ("*cofrester proffesiwn nyrsys a beydwragedd*") 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

""supplementary prescriber" ("*rhagnodydd atodol*") 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 or she is qualified to order drugs, medicines and appliances as a supplementary prescriber;";

(b) in the definition of "prescription form" ("*ffurflen bresgripsiwn*"), 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 on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998(**12**)

D.Elis-Thomas
8th October 2003 The Presiding Officer of the National Assembly

(**12**) 1998 c. 38.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make amendments to the following sets of Regulations:

1. The National Health Service (Pharmaceutical Services) Regulations 1992 ("the Pharmaceutical Services Regulations"),

2. The National Health Service (General Medical Services) 1992 ("the Medical Services Regulations") and

3. The National Health Service (Charges for Drugs and Appliances) (Wales) Regulations 2001 ("the Charges Regulations").

The changes are required as a result of the addition of a new category of prescriber of medicines and appliances for human use to the Prescription Only Medicines (Human Use) Order 1997.

This new category of prescriber is referred to as a "supplementary prescriber". Supplementary prescribers are suitably qualified nurses and registered pharmacists who will be able to prescribe prescription only medicines in accordance with an agreed clinical management plan for an individual patient. They will also be able to prescribe other medicines and appliances under such plans.

The Pharmaceutical Services Regulations contained a pre-existing category of "nurse prescriber" which is re-named by the amendments in these Regulations as an "independent nurse prescriber" to avoid confusion between the different categories of nurses who are able to prescribe medicines for human use.

The terms of service for pharmacists within the Pharmaceutical Services Regulations are also amended to enable pharmacists to dispense prescriptions issued by the new categories of prescriber.

The Medical Services Regulations are amended to apply pre-existing rules concerning the employment by a doctor of a nurse prescriber to the new category of supplementary prescriber and the re-named independent nurse prescriber. Additions are made to the Regulations to ensure that a doctor who employs a supplementary prescriber has arrangements in place to ensure compliance with the regime of control relating to this method of prescribing.

Amendments are made to the Charges Regulations to reflect the fact that supplementary prescribers may now be issuing prescription forms and may also take responsibility for prescribing for patients at walk-in centres, if the supplementary prescribers are parties to the clinical management plan for that patient.