STATUTORY RULES OF NORTHERN IRELAND

2003 No. 447

HEALTH AND PERSONAL SOCIAL SERVICES

The Health and Personal Social Services (Amendments Relating to Prescribing by Nurses and Pharmacists etc.) Regulations (Northern Ireland) 2003

Made - - - -	*13th October 2003*
Coming into operation	*5th November 2003*

The Department of Health, Social Services and Public Safety(**1**) in exercise of the powers conferred on it by Articles 56, 63(1), (2), (2A) to (2D), 64, 98, 106(b) and 107(6) and Schedule 15 to the Health and Personal Social Services (Northern Ireland) Order 1972(**2**) and of all other powers enabling it in that behalf, and in conjunction with the Department of Finance and Personnel and after consultation with such organisations as appear to the Department of Health, Social Services and Public Safety to be representative of the medical and pharmaceutical professions as required by Articles 56(5) and 63(3) of that Order, hereby makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Health and Personal Social Services (Amendments Relating to Prescribing by Nurses and Pharmacists etc.) Regulations (Northern Ireland) 2003 and shall come into operation on 5th November 2003.

(2) In these Regulations –

(a) "the Pharmaceutical Regulations" means the Pharmaceutical Services Regulations (Northern Ireland) 1997(**3**);

(b) "the General Medical Services Regulations" means the General Medical Services Regulations (Northern Ireland) 1997(**4**);

(c) "the Charges for Drugs and Appliances Regulations" means the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997(**5**).

(**1**) *See*S.I. 1999/283 (N.I.) Article 3(6)
(**2**) 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. 1991/194 (N.I. 1) Articles 31(1) and (2); 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
(**3**) S.R. 1997 No. 381 relevant amending instruments are S.R. 1999 No. 254; S.R. 2001 No. 222; S.R. 2002 No. 92 and S.R. 2002 No. 397
(**4**) S.R. 1997 No. 380; relevant amending instrument is S.R. 2001 No. 167
(**5**) S.R. 1997 No. 382; relevant amending instruments are S.R. 1999 No. 166, S.R. 2000 No. 57 and S.R. 2002 No. 397

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) 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 midwifes' 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(**6**), 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 IXB 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 IXC 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(**7**);"; 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(**8**); or

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

and against whose name is recorded in the relevant register an annotation that he is qualified to order drugs, medicines and appliances as a supplementary prescriber;";

(b) in the definition of "prescription form", in sub-paragraph (c) for "a nurse prescriber" substitute "a supplementary prescriber or independent nurse prescriber"; and

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

(3) Regulation 2(2) is omitted.

(**6**) Approved by S.I. 1983/873, to which there are amendments not relevant to these Regulations
(**7**) S.I. 2002/253
(**8**) 1954 c. 61
(**9**) S.I. 1976/1213 (N.I. 22)

(4) In Schedule 2 (terms of service for chemists) –

(a) in paragraph 2 –

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

(iv) in sub-paragraphs (9) and (10), for "dentist or nurse prescriber" substitute "dentist, supplementary prescriber or independent nurse prescriber", and

(v) in sub-paragraph (12) after "doctor" insert ", supplementary prescriber or independent nurse prescriber";

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

(c) in paragraphs 14(1), (2) and 14A, before "a nurse prescriber" at each place where it occurs, insert "supplementary prescriber or an independent".

Amendment of the General Medical Services Regulations (Northern Ireland) 1997

3.—(1) The General Medical Services Regulations are amended as follows.

(2) In regulation 2 (interpretation) the definitions of "nurse prescriber" and "professional register" shall be omitted.

(3) Regulation (2)(A) shall be omitted.

(4) 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 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 IXB 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 professional register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Nurse Prescribers' Extended Formulary in Part IXC of the Drug Tariff;";

""licensing authority" shall be construed in accordance with section 6(3) of the Medicines Act 1968(**10**);";

""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."

""the POM Order" means the Prescription Only Medicines (Human Use) Order 1997(**11**);";

""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 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 paragraph 35A(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 for "professional register" at each place where it occurs, substitute "nurses and midwives professional register";

(c) after paragraph 35A, insert the following paragraph –

"**35B.**—(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(**12**);

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

(**10**) 1968 c. 67
(**11**) S.I. 1997/1830; the relevant amending instruments are S.I. 2002/549 and S.I. 2003/696
(**12**) 1971 c. 38

(d) the medicine is not specified in an entry in column 1 of Schedule 11 to the 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 "S11".

(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,

(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 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 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 "S11";

(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 "S11".".

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

4.—(1) The Charges for Drugs and Appliances Regulations 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 Department pursuant to regulation 9 of the Pharmaceutical Services Regulations (Northern Ireland) 1997 (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 IXB 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 IXC 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;"; 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(**13**); or

(c) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(**14**),

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", in sub-paragraph (c) for "a nurse prescriber" substitute "a supplementary prescriber or independent nurse prescriber"; and

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

(3) Regulation 2(2) is omitted.

Sealed with the Official Seal of the Department of Health, Social Services and Public Safety on 13th October 2003.

L.S.

James F. Livingstone
A senior officer of the
Department of Health, Social Services and
Public Safety

(**13**) 1954 c. 61
(**14**) S.I. 1976/1213 (N.I. 22)

Sealed with the Official Seal of the Department of Finance and Personnel on 13th October 2003.

L.S.

Ciaran Doran
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, the General Medical Services Regulations (Northern Ireland) 1997 and the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997 arising out of the designation of a new category of prescriber of medicines and appliances for human use.

Regulation 2 amends the Pharmaceutical Services Regulations (Northern Ireland) 1997 ("the Pharmaceutical Services Regulations"). Under amendments to the Prescription Only Medicines (Human Use) Order 1997 "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.

Regulation 3 makes changes to the General Medical Services Regulations (Northern Ireland) 1997. As a result, the existing rules relating to the employment by doctors of "nurse prescribers" will now relate to both 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.

Regulation 4 makes changes to the Charges for Drugs and Appliances Regulations (Northern Ireland) 1997 arising out of the introduction of supplementary prescribing.