## WELSH STATUTORY INSTRUMENTS

## 2003 No. 2624

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

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

**3.**—(1) The National Health Service (General Medical Services) Regulations 1992(1) 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;";

"licensing authority" shall be construed in accordance with section 6(3) of the Medicines Act 1968(2);";

""the POM Order" means the Prescription Only Medicines (Human Use) Order 1997(**3**);";

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

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).
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<sup>(</sup>**2**) 1968 c. 67.

<sup>(3)</sup> S.I.1997/1830; the relevant amending instruments are S.I.2000/549 and 2003/696.

"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(4);
- (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,
  - (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".".