

NATIONAL ASSEMBLY FOR WALES

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

2004 No. (W.)

NATIONAL HEALTH SERVICE, WALES

**The National Health Service (Pharmaceutical Services)
(Amendment) (Wales) Regulations 2004**

EXPLANATORY NOTE

(This note is not part of the Order)

These Regulations make changes to the National Health Service (Pharmaceutical Services) Regulations 1992 which are consequential upon the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004.

2004 No. x (W.)

NATIONAL HEALTH SERVICE, WALES

**The National Health Service (Pharmaceutical Services)
(Amendment) (Wales) Regulations 2004**

Made - - - -

March 2004

Coming into force - - *In accordance with regulation 1(1)*

The National Assembly for Wales, in exercise of the powers conferred upon it by sections 41, 42, 43 and 126(4) and (5) of the National Health Service Act 1977⁽¹⁾ makes the following Regulations:

Citation, commencement, application and interpretation

1.—(1) These Regulations may be cited as the National Health Service (Pharmaceutical Services) (Amendment) (Wales) Regulations 2004 and shall come into force on 1st April 2004 except that sub-paragraph (c) of regulation 2(1), paragraphs (1) and (2) of regulation 10 and regulation 11 shall come into force immediately after the coming into force of the National Health Service (Pharmaceutical Services etc) (Repeatable Prescriptions) (Amendment) (Wales) Regulations 2004^(b).

(2) These Regulations shall apply to Wales only^(c).

(3) In these Regulations, “the principal Regulations” means the National Health Service (Pharmaceutical Services) Regulations 1992^(d).

Amendment of regulation 2 (interpretation) of the principal Regulations

2.—(1) In regulation 2(1)—

⁽¹⁾ 1977 c.49; Section 41 was substituted by the Health and Social Care Act 2001 (c.15) (“the 2001 Act”), section 42(1), and amended by the National Health Service Reform and Healthcare Professions Act 2002 (c.17) (“the 2002 Act”), Schedule 2, paragraph 13; and by the Health and Social Care (Community Health and Standards) Act 2003 (c.43) (“the 2003 Act”). Section 42 was substituted by the National Health Service (Amendment) Act 1986 (c.66), section 3(1); extended by the Health and Medicines Act 1988 (c.49), section 17; and amended by S.I. 1987/2202, article 4; by the National Health Service and Community Care Act 1990 (c.19) (“the 1990 Act”), section 12(3); by the Health Authorities Act 1995 (c.17) (“the 1995 Act”), Schedule 1, paragraph 30; by the Pharmacists (Fitness to Practice) Act 1997 (c.19), Schedule, paragraph 6; by the 2001 Act, sections 20(6), 23(5), 40(3), 43(2), (3) and (4) and by Schedule 6 Part 1; and by the 2002 Act, Schedule 2, paragraph 16. Section 43 was amended by the 1995 Act, Schedule 1, paragraph 31; by the Health Services Act 1980 (c.53), section 21(2); by the National Health Service (Primary Care) Act 1997 (c.46), section 29(1) and Schedule 2, paragraph 14; by the 1990 Act, Schedule 9, paragraph 18(2); by the 2001 Act, sections 20(7), 42(2) and 43(5); by the 2002 Act, Schedule 2, paragraph 17; and by the 2003 Act Schedule 11, paragraph 19. Section 126(5) was inserted by the 1990 Act, section 65(2); and amended by the 2001 Act, Schedule 5, paragraph 5(13)(d). *See* section 128(1) of the National Health Service Act 1977 as amended by the 1990 Act, section 26(2)(g) and (i), for the definitions of “prescribed” and “regulations”.

^(b) 2004/ (W.)

- (a) after the definition of “the 2001 Act” insert—
““the 2003 Act” means the Health and Social Care (Community Health and Standards) Act 2003(2);”,
- (b) after the definition of “the 1997 Act” insert—
““the 2004 Regulations” means the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(3);

“the Prescription of Drugs Regulations” means the National Health Service (General Medical Services Contracts)(Prescription of Drugs etc.) (Wales) Regulations 2004(4);”,
- (c) for the definition of “appropriate non-proprietary name” substitute—
““appropriate non-proprietary name” means a non-proprietary name which is not mentioned in Schedule 1 to the Prescription of Drugs Regulations or, except where the conditions in paragraph 42(2) of Schedule 6 to the 2004 Regulations are satisfied, in Schedule 2 to the Prescription of Drugs Regulations;”,
- (d) for the definition of “Community Health Council” substitute—
“a Community Health Council retained or established under section 20A of the Health (Wales) Act 2003”(e); for the definition of “doctor’s list” substitute –
““doctor’s list” means a list of a doctor’s patients kept by a Local Health Board in respect of a doctor who holds a GMS contract, in accordance with paragraph 14 of Schedule 6 to the 2004 Regulations”,
- (e) delete the definition of “doctors’ terms of service”,
- (f) after the definition of “finally granted” insert—
““GMS contract” means a general medical services contract under section 28Q(f) of the Act and “GMS contractor” shall be interpreted accordingly;”,
- (g) for the definition of “Local Medical Committee” substitute—
““Local Medical Committee” means a committee recognised under section 45A of the Act;”,
- (h) after the definition of “locality” insert—
““medical performers list” means a list of doctors prepared in accordance with regulations made under section 28X of the Act(g);”,
- (i) delete the definitions of “medical list” and “Medical Regulations”,
- (j) for the definition of “patient” substitute—
““patient” in relation to GMS contracts has the same meaning as in regulation 2 (interpretation) of the 2004 Regulations, ”,
- (k) after the definition of “preliminary consent” insert—
““prescriber” means—
(a) a doctor,
(b) an independent nurse prescriber, and

(2) c.43.
(3) S.I. 2004/291
(4) S.I. 2004/???
(e) S.I. 2004/ (W.)

- (c) a supplementary prescriber

who is a party to a GMS contract or is engaged or employed by a GMS contractor, “

- (l) in the definition of “prescription form”, for the words “and issued by a doctor, dentist, supplementary prescriber or independent nurse prescriber” substitute the words “and issued by a prescriber or a dentist”.

- (2) For regulation 2(1B) substitute—

“In these Regulations—

- (a) the term “pharmaceutical services”, in relation to a doctor whose name is not included in a medical performers list, but who is a party to a GMS contract, means those services referred to in regulation 20; and
- (b) the term “dispensing services”, in relation to such a doctor means, any corresponding service performed, not as pharmaceutical services, but under the terms of a GMS contract which gives effect to paragraphs 47 to 51 of Schedule 6 to the 2004 Regulations which gives effect to paragraphs 26 to 40 of Schedule 5 to the PMS Regulations.”.

- (3) After regulation 2(3)(b) insert—

“(c) For as long as there are in existence contracts entered into under Article 12 of the General Medical Services Transitional and Consequential Provisions (Wales) Order 2004⁽⁵⁾ (“default contracts”) in respect of such contracts any reference to a GMS contract shall be read as including a reference to a contract entered into under that Article and any reference to a term of a GMS contract shall be read as including a reference to the equivalent term in the default contract.”.

Amendment of regulation 6 (determination of applications) of the principal Regulations

3. For regulation 6(6) substitute—

“No person who holds a GMS contract, or is a legal and beneficial shareholder, director or company secretary of a company which holds a GMS contract, or is employed or engaged by a person who holds such a contract. shall take part in any decision under this regulation.”.

Amendment of regulation 9 (determination of controlled locality) of the principal Regulations

- 4.—(1) In regulation 9(5), after the word “doctor” insert “, general medical services contractor”.

- (2) For regulation 9(6) substitute—

“Where the Local Health Board determines that any area or part of an area is or is not rural in character, it shall consider whether the provision of primary medical services by any doctor, GMS contractor, or pharmaceutical services by any chemist, is likely to be adversely affected in consequence of that determination.”.

⁽⁵⁾ S.I. 2004/477(W.47).

(3) For regulation 9(7) substitute–

“Where the Local Health Board considers that the provision of primary medical services by any doctor, GMS contractor, or pharmaceutical services by any chemist, is likely to be adversely affected in consequence of a determination under paragraph (4), it may impose conditions to postpone, for such period as it thinks fit, the making or termination of arrangements under regulation 20 for the provision by a doctor of pharmaceutical services to his patients.”.

Amendment of regulation 12 (determination of applications in respect of controlled localities) of the principal Regulations

Local Health Board, who, in its opinion, might be affected by the grant of the application;”.

4.-(1) For regulation 12(1)(c) substitute–

“any person who holds a GMS contract or whose name is included in the pharmaceutical list of the Local Health Board who, in its opinion, might be affected by the grant of the application;”.

(2) For regulation 12(1)(d) substitute–

“any other Local Health Board with whom a person who holds a GMS contract, who might in its opinion, be affected by the applications.”.

(3) In regulation 12(1)(e) for the words “Community Health Council” substitute the words “Patients’ Forum”.

(4) For regulation 12(2)(c) substitute–

“(c) any person who holds a GMS contract or is a party to a PMS agreement or whose name is included in the pharmaceutical list, or who provides local pharmaceutical services under a pharmacy pilot scheme entered into by that Primary Care Trust, who might, in its opinion, be affected by the grant of the application.”.

(5) For regulation 12(10) substitute–

“No person who holds a GMS contract, or is a legal and beneficial shareholder, director or company secretary of a company which holds a GMS contract, or is employed or engaged by a person who holds such a contract shall take part in any decision under this regulation.”.

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(6) In regulation 12(13)(a), for the words “general medical services, personal medical services” substitute “primary medical services”.

(7) In regulation 12(13)(c), for the words “general medical services, personal medical services” substitute “primary medical services”

(8) In regulation 12(14), for the words “general medical services or personal medical services by any doctor” substitute “primary medical services in its area”.

(9) In regulation 12(15) for the words “general medical services, or personal medical services by any doctor” substitute “primary medical services in its area”.

Amendment of regulation 13 (appeals in connection with determination under regulation 12) of the principal Regulations

5. For regulation 13(2)(a)(ii) substitute–

“any person who holds a GMS contract , or whose name is included in the pharmaceutical list of the Local Health Board or any other Local Health Board to which a copy of the application was sent under regulation 12(1)(d),”.

Amendment of regulation 20 (arrangements for provision of pharmaceutical services by doctors) of the principal Regulations

6. For regulation 20 substitute–

“(1) Where a patient–

- (a) satisfies a Local Health Board that he or she would have serious difficulty in obtaining any necessary drugs or appliances from a pharmacy by reason of distance or inadequacy of means of communication; or
- (b) is resident in a controlled locality, at a distance of more than one mile from any pharmacy, and one of the conditions specified in paragraph (2) is satisfied in his case,

he or she may at any time request in writing the doctor *who is, or who is engaged or employed by, the GMS contractor* on whose doctor’s list the patient is included to provide him with pharmaceutical services.

(2) The conditions referred to in paragraph (1)(b) are–

(a) that–

- (i) there is in effect an outline consent granted to that doctor or to another doctor or any previous doctor in his practice in respect of the area in which the patient resides; and
 - (ii) any conditions imposed under regulation 12(15) or regulation 13(13)(b) in connection with that grant are such as to permit arrangements to be made under this regulation for the provision of pharmaceutical services by that doctor to the patient; or
- (b) immediately before these Regulations came into force arrangements or requirements were in effect under regulations revoked by these Regulations for that doctor or his partner or any previous doctor in his practice to provide drugs or appliances to patients, and the patient–
- (i) has not previously been included in a doctor’s list, or
 - (ii) has changed his address from that last notified to the Local Health Board, or
 - (iii) has not changed his address but, immediately before his acceptance as a patient by that doctor, was being provided with pharmaceutical services by a doctor pursuant to an arrangement or requirement under these Regulations.

(3) If a doctor so requested by a patient, under paragraph (1)–

- (a) applies to provide pharmaceutical services to the patient, and sends with his application the patient’s request in writing, the Local Health Board shall make arrangements with him for the provision of such services by him; or
- (b) does not so apply within 30 days, the Local Health Board may, subject to paragraph (5), require him to undertake such provision and shall give him notice in writing to that effect.

(4) An arrangement made by a Local Health Board under paragraph (3)(a) shall–

- (a) have effect from the date of the patient’s request in writing; and
- (b) enable that doctor, any other doctor in his practice or any doctor who subsequently joins his practice to provide pharmaceutical services for the patient so long as the arrangement remains in effect.

(5) A Local Health Board shall not under paragraph (3)(b) require a doctor to provide pharmaceutical services to a person on the *relevant doctor’s list* for that doctor if that doctor satisfies the Local Health Board, or on appeal, the Assembly that–

- (a) he or she does not normally provide pharmaceutical services under this regulation; or

- (b) in the case of a person to whom paragraph (1)(b) applies, the person would not have serious difficulty, by reason of distance or inadequacy of means of communication, in obtaining drugs and appliances from a pharmacy.
- (6) A Local Health Board shall give a doctor reasonable notice–
 - (a) that it requires the doctor to provide pharmaceutical services to any person; or
 - (b) subject to paragraph (7), that, where a person no longer satisfies the provisions of paragraph (1), the doctor shall discontinue the provision of pharmaceutical services to that person.
- (7) A notice under paragraph (6)(b)–
 - (a) shall be subject to any postponement or termination of arrangements for the provision of pharmaceutical services to that person by that doctor made under regulation 12(15) or 13(13); and
 - (b) shall not be given–
 - (i) pending any appeal against a decision by a Local Health Board to postpone the making or termination of such arrangements, or
 - (ii) where regulations 9(10) so requires.
- (8) Notwithstanding paragraph (3), where a drug or appliance is one for which a doctor is entitled to an additional payment if he provides it, he may, with the consent of the patient, instead of providing it himself, order it by issuing a prescription form by electronic means or by issuing a prescription to the patient in accordance with *paragraph 39 of Schedule 6 to the 2004 Regulations*
- (9) Where under any provision of regulations revoked by, and not re-enacted in, these Regulations an arrangement or requirement for a doctor to provide drugs or appliances to a patient was in effect immediately before these Regulations came into force, that arrangement or requirement shall have effect as though made under this regulation notwithstanding that neither of the conditions specified in paragraph (2) is satisfied.
- (10) A doctor who provides pharmaceutical services to some or all of the patients on *the relevant doctor's list* in accordance with this regulation may provide any necessary pharmaceutical services to a person whom he has accepted as a temporary resident *under the 2004 Regulations*.
- (11) An appeal under paragraph (5) shall be made in writing within 30 days from the date on which notice of the decision was sent to the doctor and shall contain a concise statement of the grounds of appeal.
- (12) The Assembly shall, on receipt of any notice of appeal under this regulation, send a copy of that notice to the Local Health Board *and the relevant GMS contractor* and the Local Health Board *and relevant GMS contractor* may, within 30 days from the date on which the Assembly sent a copy of the notice of appeal, make representations in writing to it.
- (13) The Assembly may determine an appeal pursuant to paragraph (5) in such manner as he thinks fit.
- (14) The Assembly shall, upon determination by it of an appeal under this regulation, give notice of its decision in writing, together with the reasons for it, to the appellant, to the Local Health Board *and to the relevant GMS contractor*.
- (15) Any question whether a substance provided by a doctor was a drug, the provisions of which formed part of pharmaceutical services under the Act, shall be determined in accordance with *regulation 36 of the Medical Regulations* and the provisions of that regulation shall apply according as though references to–
 - (a) the doctor who ordered the substance were to the doctor who provided it; and
 - (b) the person to whom the order was given were to the person to whom the substance was provided.
- (16) In this section–

“relevant doctor’s list” means the doctor’s list for that doctor where he or she is a party to a GMS contract or, where he or she is not such a party, means the list for the party to the GMS contract by whom he or she is engaged or employed,
“relevant GMS contractor” means the GMS contractor by whom the doctor is employed or engaged.

Amendment of regulation 21B (dispensing doctor lists) of the principal Regulations

7. For regulation 21B substitute—

“(1) A Local Health Board shall prepare and publish a list, to be called the dispensing doctor list, of the names of those doctors authorised or required by the Local Health Board under regulation 20 to provide pharmaceutical services to their patients and who are actually doing so.

(2) The dispensing doctor list shall indicate the address *of the practice from which any doctor whose name is included provides primary medical services.*”

Amendment of regulation 21C of the principal Regulations

8. For regulation 21C(1) substitute—

“A Local Health Board shall remove the name of a doctor from its dispensing doctor list when—

- (a) the doctor has died; or
- (b) the doctor is no longer *providing primary medical services*; or
- (c) more than 12 months have elapsed since the doctor last provide pharmaceutical services pursuant to the authorisation or requirement to provide such services given by the Local Health Board under regulation 20.”

Amendment of Part I(General) of Schedule 2 to the principal Regulations

9. In paragraph 1(2) of Schedule 2—

(a) insert—

““repeatable prescriber” means a prescriber who is—

- (a) a GMS contractor who provides repeatable prescribing services under the terms of its contract which give effect to paragraph 40 of Schedule 6 to the 2004 Regulations;

or

- (b) employed or engaged by one of the persons specified in paragraph (a) or (b).”

Amendment of Part II (terms of service for chemists) of Schedule 2 to the principal Regulations

10. —(1) For paragraph 3(1) of Schedule 2 substitute—

“Where any person presents on a prescription form—

- (a) an order for drugs, not being Scheduled drugs, or appliance, not being restricted availability appliances, signed by a prescriber; or
- (b) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, signed by, and endorsed on its face with the reference “SLS” by a prescriber; or

- (c) an order for a restricted availability appliance, signed by and endorsed on its face with the reference “SLS” by a prescriber; or
- (d) an order for listed drugs or medicines, signed by a dentist or his deputy or assistant,

a chemist shall, with reasonable promptness, provide the drugs or medicines so ordered, and such of the appliances so ordered as he supplies in the normal course of his business.”

(2) For paragraph 3(1ZA)(a) of Schedule 2 substitute—

“presents a repeatable prescription which contains—

- (i) an order for drugs, not being Scheduled drugs or controlled drugs within the meaning of the Misuse of Drugs Act 1971⁽⁶⁾, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001⁽⁷⁾, signed by a repeatable prescriber,
- (ii) an order for a drug specified in Schedule 2 to the Prescription of Drugs Regulations, not being a controlled drug within the meaning of the Misuse of Drugs Act 1971, other than a drug which is for the time being specified in Schedule 4 or 5 to the Misuse of Drugs Regulations 2001, signed by and endorsed on its face with the reference “SLS” by a repeatable prescriber,
- (iii) an order for appliances, not being restricted availability appliances, signed by a repeatable prescriber, or
- (iv) an order for a restricted availability appliance, signed by, and endorsed on its face with the reference “SLS” by a repeatable prescriber,

and also presents and associated batch issue; ”.

(3) In paragraph 3(4) of Schedule 2, for the words “a doctor, a dentist, a supplementary prescriber or an independent nurse prescriber” substitute “a prescriber or a dentist”.

(4) In paragraph 3(6) of Schedule 2, for the words “a doctor, dentist, supplementary prescriber or independent nurse prescriber” substitute “a prescriber or dentist”.

(5) In paragraph 3(7) of Schedule 2, for the words “the doctor, dentist, supplementary prescriber or independent nurse prescriber” substitute “the prescriber or dentist”.

(6) In paragraph 3(9), for the words “doctor, supplementary prescriber or independent nurse prescriber” whenever they appear substitute “prescriber”.

11.—(1) In paragraphs 3A and (7) of Schedule 2, for the word “doctor” whenever it appears, substitute “prescriber”.

(2) In paragraph 3A(9)(c) for the words “repeatable prescribing doctor” substitute the words “repeatable prescriber”.

12. For paragraph 7(2) of Schedule 2, substitute—

“Where a chemist supplies a container in response to an order for drugs signed by a prescriber under paragraph 39 of Schedule 6 to the 2004 Regulations, or supplies an oxygen container or oxygen equipment, other than equipment specified in the Drug Tariff as not returnable to the chemist, the container and equipment shall remain the property of the chemist.”.

Amendment of Part III (terms of service for doctors who provide pharmaceutical services) of Schedule 2 to the principal Regulations

13. For paragraph 11 of Schedule 2 substitute—

⁽⁶⁾ 1971 c.38
⁽⁷⁾ S.I. 2001/3998

“Subject to paragraph 11A, where a doctor is authorised or required by a Local Health Board under regulation 20 to provide drugs or appliances to a patient—

- (a) he shall record an order for the provision of any drugs, or appliances which are needed for the treatment of the patient on a prescription form completed in accordance with the term of a GMS contract which gives effect to paragraph 39(3) of Schedule 6 to the 2004 Regulations;
- (b) he shall provide those drugs or appliances in a suitable container;
- (c) he shall provide for the patient a drug specified in Schedule 2 to the Prescription of Drugs Regulations only where the conditions in paragraph 42(2) of Schedule 6 to the 2004 Regulations are satisfied; and
- (d) he shall provide for the patient a restricted availability appliance only if the patient is a person, or it is for a purpose, specified in the Drug Tariff.”.

14. For paragraph 11A(2) of Schedule 2 substitute—

“Where a patient presents an order on a prescription form for drugs or medicines or listed appliances signed by a prescriber, or an order for a restricted availability appliance signed by and endorsed on its face with the reference “SLS” by a prescriber, to a doctor who is authorised or required by regulation 20 to provide drugs or appliances to that patient, the doctor may provide to the patient such of the drugs, medicines or appliances so ordered as he supplies in the normal course of his practice.”.

15.—(1) For paragraph 13(1) of Schedule 2 substitute—

“The terms of a GMS contract giving effect to Regulation 24 and Schedule 5 of the 2004 Regulations (fees and charges) apply in respect of the provision of any drugs or appliances by a doctor as they apply in respect of prescriptions for drugs and appliances.”

(2) For paragraph 13(2) of Schedule 2 substitute—

“Where a doctor who is authorised or required by a Local Health Board under regulation 20 to provide drugs or appliances provides a drug or appliance under pharmaceutical services—

- (a) in accordance with this Part; and
- (b) had the drug or appliance been provided by a contractor providing dispensing services under a GMS contract, the contractor would have been entitled to a payment in respect of the drug or appliance by virtue of directions given by the Assmebly under section 28T(8) of the Act,

the Local Health Board shall credit him with the payment.”

16. For paragraph 14 of Schedule 2 substitute—

“(1) A doctor who is authorised or required by a Local Health Board under regulation 20 to provide drugs or appliances to a patient, or who otherwise provides pharmaceutical services, shall secure that the complaints procedure established in accordance with the terms of a GMS contract which gives effect to paragraph 92 of Schedule 6 to the 2004 regulations, by the doctor if he is a party to that GMS contract or by the contractor by whom he is employed or engaged if he is not a party to that GMS contract, applies in relation to any matter reasonably connected with his provision of pharmaceutical services as tit applies as respects to services provided under that GMS contract.

(2) Accordingly, the term of the GMS contract which gives effect to paragraph 95 of Schedule 6 to the 2004 Regulations also applies in relation to complaints about such matters.”.

(8) Section 28T was inserted by section 175(1) of the 2003 Act
(b) 1998 c.38.

Provisions to be revoked

17. The provisions of the Principal Regulations set out in the Schedule are revoked to the extent specified.

Signed on behalf of the National Assembly for Wales under section 66(1) of the Government of Wales Act 1998 **(b)**.

SCHEDULE 1

Regulation 17

Provisions of the Principal Regulations to be Revoked

<i>Provision to be revoked</i>	<i>Extent of Revocation</i>
Regulation 2(1)	The definitions of: “doctors’ terms of service” “medical list” “Medical Regulations”
[Regulation 20	sub-paragraph (15)]
Schedule 2	sub-paragraph 13(3)