WELSH STATUTORY INSTRUMENTS

2004 No. 1021 (W.118)

NATIONAL HEALTH SERVICE, WALES

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

Made - - - - 30th 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(**2**).

(2) These Regulations shall apply to Wales only.

(3) In these Regulations, "the principal Regulations" means the National Health Service (Pharmaceutical Services) Regulations 1992(**3**).

(**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 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 Pharmacists (Fitness to Practice) Act 1997 (c. 19), Schedule, paragraph 6 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".

(**2**) 2004/1018 (W.115)

(**3**) S.I. 1992/662; relevant amending instruments are S.I. 1993/2451, 1994/2402, 1995/644, 1996/698, 1998/681 and 2224, 1999/696, 2001/1396, 2002/3189 (W.305) and 2003/3236 (W.316).

Amendment of regulation 2 (interpretation) of the principal Regulations

2.—(1) In regulation 2(1)—

(a) after the definition of "the 2001 Act" insert—

""the 2003 Act" means the Health and Social Care (Community Health and Standards) Act 2003(**4**);",

(b) after the definition of "the 1997 Act" insert—

""the 2004 Regulations" means the National Health Service (General Medical Services Contracts) (Wales) Regulations 2004(**5**);

"the Prescription of Drugs Regulations" means the National Health Service (General Medical Services Contracts)(Prescription of Drugs etc.) (Wales) Regulations 2004(**6**);",

(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**);

(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",

(f) delete the definition of "doctors' terms of service",

(g) after the definition of "finally granted" insert—

""GMS contract" means a general medical services contract under section 28Q of the Act and "GMS contractor" shall be interpreted accordingly;",

(h) for the definition of "Local Medical Committee" substitute—

""Local Medical Committee" means a committee recognised under section 45A of the Act;",

(i) 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;",

(j) delete the definitions of "medical list" and "Medical Regulations",

(k) 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, ",

(l) after the definition of "preliminary consent" insert—

""prescriber" means—

(a) a doctor,

(b) an independent nurse prescriber, and

(**4**) 2003 c. 43.
(**5**) S.I. 2004/291
(**6**) S.I. 2004/1022 (W.119).

(c) a supplementary prescriber

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

(m) 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(**7**) (“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.”.

(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.”.

(**7**) S.I. 2004/477(W.47).

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

5.—(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.".

(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

6. 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

7. 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.